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Choosing Medical Malpractice

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CHOOSING MEDICAL MALPRACTICE

Nadia N. Sawicki*

Abstract: Modern principles of patient autonomy and health care consumerism are at odds with medical malpractice law's traditional skepticism towards the defenses of contractual waiver and assumption of risk. Many American courts follow a patient-protective view, exemplified by the reasoning in the seminal *Tunkl* case, rejecting any attempts by physicians to relieve themselves of liability on the grounds of a patient's agreement to assume the risk of malpractice. However, where patients pursue unconventional treatments that satisfy their personal preferences but that arguably fall outside the standard of care, courts have good reason to be more receptive to such defenses. This Article fills an important gap in the scholarly debate about whether patients and physicians should be able to modify their default duties under tort law, demonstrating that two lines of rarely-acknowledged cases—dealing with alternative therapies and Jehovah's Witness blood refusals—lend support to the principle that patients who choose malpractice should be limited in their right to tort recovery.

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INTRODUCTION

There is a long-standing debate about whether physicians and patients ought to be able to contractually modify their default obligations under tort law. One of the core issues in this debate is whether agreements purporting to release physicians from liability for malpractice are enforceable. Closely related is the issue of whether, in the absence of an express waiver of liability, courts ought to recognize the defense of implied assumption of risk in malpractice actions. Both inquiries speak to the fundamental question of whether patients should retain a right of recovery if they voluntarily choose to accept—either explicitly or implicitly—the risks of negligent medical care.

Traditionalists view the doctor-patient relationship as fiduciary in nature, and argue that releasing physicians from liability for malpractice on the basis of a patient's voluntary choice should be prohibited as a matter of policy because of the significant disparity in bargaining power between doctor and patient.[1] Economists and others, however, argue that allowing physicians and patients to shift the allocation of risk as they see

1. *See infra* section II.B.2.

fit is necessary to achieve efficiencies that meaningfully benefit both parties.[2] Still other commentators fall somewhere between these two extremes, arguing that physicians should be able to rely on contract- or tort-based defenses grounded in a patient's voluntary acceptance of risk only if certain conditions are satisfied.[3]

Much of the scholarship in this area either asserts or presumes that American courts follow the traditionalist view and rejects any attempts by physicians to relieve themselves of liability on the grounds of a patient's agreement to assume the risk of malpractice.[4] But, as some authors have recognized, the case law by no means establishes a categorical prohibition. While most courts do ultimately reject defenses based on contract or assumption of risk in medical malpractice cases, a position exemplified by the widely cited *Tunkl*[5] case, they often do so only after carefully examining the characteristics of the patient's acceptance—an adjudicative approach that is inconsistent with a categorical bar.[6] More importantly, there are a surprising number of cases in which courts have allowed physicians to present such defenses—cases involving experimental or alternative therapies, and cases involving Jehovah's Witness patients who request surgery without the use of blood or blood products.

Few authors meaningfully acknowledge these important lines of precedent or consider their implications.[7] Those who do cite these cases

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2. *See infra* section I.C.

3. *See infra* note 89.

4. *See, e.g.*, Richard A. Epstein, *Medical Malpractice, Imperfect Information, and the Contractual Foundation for Medical Services*, 49 L. & CONTEMP. PROBS. 201, 205 (1986) (referring to "courts' hostility towards all private contracts regulating the risk of medical injuries"); Leonard J. Nelson III, Helling v. Carey *Revisited: Physician Liability in the Age of Managed Care*, 25 SEATTLE U. L. REV. 775, 785 (2002) ("Traditionally, our courts have been unwilling to allow contract law to displace tort law in cases involving iatrogenic injury. Tort law imposes certain obligations notwithstanding agreements reached by the parties."); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 908 (1993) ("Tort law has largely eclipsed consent-contract approaches to the problem of health-care-related injuries."); Alex Stein, *Toward a Theory of Medical Malpractice*, 97 IOWA L. REV. 1201, 1236 n.191 (2012) (noting that "[c]ontracts purporting to . . . reduce doctors' responsibility for malpractice are not enforceable: courts void such contracts on public policy grounds").

5. Tunkl v. Regents of Univ. of Cal., 383 P.2d 441 (Cal. 1963).

6. Matthew J. B. Lawrence, *In Search of an Enforceable Medical Malpractice Exculpatory Agreement: Introducing Confidential Contracts as a Solution to the Doctor-Patient Relationship Problem*, 84 N.Y.U. L. REV. 850, 855–59 (2009) (noting that some cases analyzing exculpatory agreements in the medical malpractice context engage in "case-by-case analysis" of "particular bargaining dynamics" and specific contractual language).

7. Most articles citing these cases do so only tangentially, or in footnotes. *But see* Mark A. Hall, *Paying for What You Get and Getting What You Pay for: Legal Responses to Consumer-Driven Health Care*, 69 L. & CONTEMP. PROBS. 159, 178–79 (2006) (discussing whether "patients'

often refer to them as "exceptional" or "bizarre," dismissing them as anomalies in an otherwise consistent doctrine barring limitations on liability in malpractice actions.[8] Very few scholars have made serious attempts to reconcile the outcomes of these cases with the traditionalist model, or to offer doctrinal justifications for courts' more accommodating attitude towards these defenses in some contexts.[9]

This Article argues that it is a mistake to dismiss this line of cases as mere footnotes in the jurisprudence, and that scholars should treat these contractual and tort law defenses to medical malpractice liability seriously. Rather, it is essential to understand why courts have been receptive to the argument that patients can, in some contexts, be deemed to have accepted the risk of harm arising from a physician's negligent conduct. The outcomes in these cases more accurately reflect the principles of patient autonomy upon which the modern doctrine of informed consent is grounded, and so offer a valuable counterpoint to the paternalistic and protectionist attitudes inherent in the traditionalist model—a counterpoint that is particularly relevant in light of the modern trend towards consumerism in American health care.

This Article analyzes the objections traditionally leveled against attempts to limit patients' right of recovery in malpractice cases and demonstrates why these objections carry less weight in the contexts of experimental or alternative therapies and religiously directed treatment. More importantly, it also demonstrates that the best justifications for limiting patients' right to recovery in these narrow situations would also apply to many other contexts in which patients pursue unorthodox

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informed acceptance of substandard care is a liability defense," and recognizing "several lines of doctrine" to this effect); Mark A. Hall & Carl E. Schneider, *When Patients Say No (to Save Money): An Essay on the Tectonics of Health Law*, 41 CONN. L. REV. 743, 762–64 (2008) (arguing that waiver of liability and assumption of risk doctrines do not adequately protect physicians whose patients seek out low-cost treatment and discussing *Schneider v. Revici* as an illustrative case); Maxwell J. Mehlman, *Fiduciary Contracting: Limitations on Bargaining Between Patients and Health Care Providers*, 51 U. PITT. L. REV. 365 (1989) (analyzing the assumption of risk and waiver cases discussed in this Article through the lens of fiduciary contracting).

8. *See, e.g.*, Anna B. Laakmann, *When Should Physicians Be Liable for Innovation*, 36 CARDOZO L. REV. 913, 942, 966 (2014) (describing *Boyle v. Revici*, *Schneider v. Revici*, and *Colton v. New York Hospital* as "notable exception[s]" to courts' typical rejection of assumption of risk defenses and contractual waivers in medical malpractice cases); Lawrence, *supra* note 6, at 875 (describing *Schneider v. Revici* as "an otherwise strange exception to the categorical rule [barring waivers]"); Mehlman, *supra* note 7, at 411–12 (describing the decision in *Schneider v. Revici* as "bizarre" and "perplexing").

9. One notable exception is Maxwell Mehlman, who skillfully analyzes the cases discussed in section II.C through the lens of fiduciary contracting and concludes that their outcomes are justified by the fact that the agreements in these cases satisfy the conditions for effective contracting—freedom of choice and adequacy of information. Mehlman, *supra* note 7, at 401–14.

treatment that arguably falls outside the standard of care. Thus, contract- and tort-based defenses based on a patient's voluntary acceptance of risk should gain greater traction as patients with consumerist mindsets increasingly seek out services that fall outside the medical mainstream and that physicians may be unwilling to provide in the absence of liability protection. These may include not only experimental and alternative therapies and medical care guided by religious dictates, but also services like adjusted vaccination schedules, low-cost or low-intensity care plans, requests for medically unnecessary tests and treatments, as well as highly controversial interventions like elective amputation and sexual orientation change efforts.[10]

The expansion of courts' reasoning in alternative therapy and Jehovah's Witness cases to other types of patient-directed care is both natural and necessary. American law permits patients to exercise their autonomy interests by pursuing unorthodox medical treatments that are freely available on the market—even treatments that fall outside the standard of care. The common law of informed consent is grounded in the principle that patients are able to comprehend and evaluate the risks and benefits of their treatment options. It would seem consistent with these foundational principles to limit a patient's ability to sue when she makes a voluntary and informed choice to accept medical treatment that constitutes malpractice, and her physician provides that treatment in accordance with the patient's expectations. That said, expansion of physicians' ability to rely on contract- and tort-based defenses in cases of "malpractice by choice" must be mediated by additional patient protections.

Part I of the Article briefly describes the development of modern informed consent doctrine and the trend towards consumerist attitudes and behaviors in the U.S. health care system, including the resulting increase in patient requests for treatments that push the boundaries of conventional medical practice. It draws a connection between the shift away from medical paternalism towards patient autonomy, and legal scholars' efforts to move the law in a similar direction by allowing contractual modifications to physicians' default duties under tort law.

Part II explains how contractual waivers of liability and the tort doctrine of assumption of risk might be used by health care providers to limit liability in medical malpractice actions. It seeks to make a significant contribution to the literature in this area by not only providing an account of the traditional view rejecting these defenses, but

10. *See infra* section I.B.

also comprehensively tracking and analyzing the cases in which courts have been receptive to such defenses.

Part III seeks to reconcile the inconsistency between the strength of courts' and commentators' objections to contractual- and tort-based limitations on malpractice liability, and their apparent willingness to dismiss these objections in alternative therapy and Jehovah's Witness cases. It demonstrates that, although the judicial reasoning in these cases is strikingly weak, there are in fact good reasons why courts would be willing to limit patients' right to recovery in these two contexts. However, this Part demonstrates that these reasons would apply equally well to many other contexts in which patients knowingly seek out unorthodox treatment that a jury might conclude falls outside the standard of care, provided certain conditions are satisfied—namely, that the patient is fully informed of the medical risks and benefits of the selected treatment and its alternatives; the risks that ultimately arise are those inherent in the treatment and not caused by unanticipated error; and the legal fact finder concludes there is some societal value in this unorthodox treatment.

Part IV concludes by addressing the concerns that might arise were courts to extend their reasoning in alternative therapy and Jehovah's Witness cases to other contexts of consumer-directed care. First, it demonstrates that a pure application of tort and contract law may be inadequate to fully protect patients in light of the fiduciary duties owed to them by physicians. Thus, it recommends that the use of assumption of risk and contract-based defenses in cases of "malpractice by choice" ought to be conditioned on the physician's satisfaction of his informed consent duties (including his duty to disclose personal conflicts of interest), and on his disclosure of the fact that the treatment the patient has selected falls outside the medical standard of care. Second, this Part recognizes the concern that, in the absence of malpractice liability, physicians may have fewer incentives to practice within the standard of care but demonstrates the limitations of this objection. It concludes that there are alternative mechanisms by which the medical profession can enforce quality standards that do not result in tort compensation for patients who voluntarily choose to pursue non-standard medical treatments with full knowledge of their risks.

I. MOVING TOWARDS PATIENT AUTONOMY IN MEDICINE AND LAW

In the second half of the twentieth century, paternalistic medical practices gave way to a newfound appreciation for principles of patient autonomy. Law and ethics both drove changes to medical practice,

establishing a new duty on the part of physicians to obtain a patient's informed consent before proceeding with treatment.

This increased emphasis on patient autonomy went hand-in-hand with a new view of patients as active consumers of health care. As medicine advanced and treatment options expanded, patients found themselves able to make choices based on their personal values and preferences.[11] And while patients were previously dependent on their physicians for information about medical conditions and treatment options, the internet brought greater access to information and gave them the tools to self-diagnose, learn about treatment options, and choose between providers.[12]

Today, providers report an increase in patients actively seeking out specific tests and treatments—whether branded pharmaceuticals advertised on television, experimental or alternative therapies reported in the media, or tests to confirm self-diagnoses based on internet research. And some patients, in seeking out treatment consistent with their values and beliefs, may request services that fall outside the medical mainstream. Examples of such patient-requested care include experimental treatment, complementary and alternative therapy, modified vaccination schedules, treatment guided by religious beliefs, and low-cost or low-intensity care. Some of these services are in fact medically appropriate and supported by evidence but rarely available due to liability concerns,[13] while others are so clearly beyond the standard of care that they qualify as quackery.[14]

This shift towards a consumerist model of health care was also reflected in legal debate. Scholars of law and economics argued that, just

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11. The term "preference-sensitive care" is used to describe situations in which "two or more medically acceptable options exist and choice should depend on patient preferences." John E. Wennberg, *Unwarranted Variations in Healthcare Delivery: Implications for Academic Medical Centres,* 325 BRITISH MED. J. 961, 962 (2002).

12. Of course, the quality of health information on the internet varies widely, and patients are not well-served by uncritical reliance on online resources. *See generally* Ahmad Risk & Carolyn Petersen, *Health Information on the Internet: Quality Issues and International Initiatives*, 287 JAMA 2713 (2002).

13. One example is vaginal birth after cesarean (VBAC), a practice that the American College of Obstetricians and Gynecologists describes as safe and appropriate for many women with previous cesarean deliveries. Am. Coll. Obstetricians & Gynecologists, *ACOG Practice Bulletin No. 115: Vaginal Birth After Previous Cesarean Delivery*, 116 OBSTETRICS & GYNECOLOGY 450, 450 (2010). Nevertheless, many providers and institutions refuse to offer VBAC as a result of liability concerns, among other reasons. Farah Diaz-Tello, *When the Invisible Hand Wields a Scalpel: Maternity Care in a Market Economy*, 18 CUNY L. REV. 197, 210–13 (2015); Elizabeth Kukura, *Choice in Birth: Preserving Access to VBAC*, 114 PENN ST. L. REV. 955, 967–70 (2009).

14. *See, e.g.*, Charell v. Gonzalez, 660 N.Y.S.2d 665 (N.Y. Sup. Ct. 1997) (upholding $4 million jury verdict against a physician whose treatment for a patient with uterine cancer included six daily coffee enemas).

as autonomous patients might have varying preferences about health care treatment, so too might they have varying preferences regarding legal protection from medical malpractice.[15] Rather than deferring to the standard set of rights and duties traditionally set by tort law, these scholars argued, both patients and physicians would be better served if they were free to choose contractual terms that satisfied their autonomous preferences.[16]

This Part briefly describes the historical development of the doctrine of informed consent,[17] explains how the principle of autonomy upon which the doctrine is based went hand-in-hand with the trend towards health care consumerism, and describes the challenges physicians face when patients request care that falls outside the medical mainstream. It then draws a connection between the increased recognition of patient autonomy in medical decision-making and the push by legal scholars to move the law in a similar direction by recognizing patients' right to freely contract with their physicians.

A. Informed Consent and Its Theoretical Underpinnings

Until the second half of the twentieth century, medicine was a fundamentally paternalistic profession.[18] Driven by the ethical principles of beneficence and non-maleficence, physicians diagnosed patients and administered treatments with very little active participation by patients.[19] It was not until the atrocities of Nazi physicians came to light at the Nuremberg Trials of the late 1940s that public attention was drawn to the need to protect patients from abuse by physicians.[20]

American common law had long recognized that physicians may be liable for battery if they performed treatment without a patient's consent.[21] But the 1950s and 1960s brought new developments in the law's approach to patient rights. Courts began to recognize not only physicians' basic duty to secure a patient's consent to medical treatment,

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15. *See infra* section I.C.

16. *See infra* section I.C.

17. For a fuller account of the history of the legal and ethical doctrines of informed consent, see RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (1986).

18. JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 20–21 (2002).

19. Timothy E. Quill & Howard Brody, *Physician Recommendations and Patient Autonomy: Finding a Balance Between Physician Power and Patient Choice*, 125 ANNALS INTERNAL MED. 763, 763–64 (1996).

20. FADEN & BEAUCHAMP, *supra* note 17, at 87.

21. *See, e.g.*, Mohr v. Williams, 104 N.W. 12 (Minn. 1905); Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92 (N.Y. 1914).

but also a duty to ensure that the patient's consent was granted based on full understanding of the risks and benefits of treatment.[22] Thus, even if a patient agreed to treatment and so could not bring a battery action, she could bring a negligence action for the physician's failure to obtain informed consent. These legal developments were driven in part by the patients' rights movement, which emphasized the importance of autonomy in medical decision-making.[23] Principles of medical ethics also shifted to give greater weight to the medical profession's duty to promote patient autonomy, rather than focusing on the traditional principles of beneficence and non-maleficence.[24]

The modern legal and ethical doctrines of informed consent establish that patients have a right to be fully informed before consenting to many forms of medical treatment. Physicians, therefore, have a duty to disclose the risks and benefits of the treatment in question, the risks and benefits of reasonable alternative treatments, and the risks and benefits of taking no action. While these duties were originally established by common law, many states now have statutes detailing physicians' duties in this regard and establishing remedies for patients whose rights are violated.[25]

Today, some argue that the pendulum has swung too far in the direction of patient autonomy, to the detriment of other important ethical values.[26] Others argue that the practical implementation of informed consent doctrine is fundamentally flawed, and that providing patients with information about treatment choices may not in fact serve their best

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22. JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND PRACTICE 44–46 (2d ed. 2001); FADEN & BEAUCHAMP, *supra* note 17, at 86–91; Jay Katz, *Reflections on Informed Consent: 40 Years After Its Birth*, 186 J. AM. COLL. SURGEONS 466, 467–68 (1998).

23. *See* BERG ET AL., *supra* note 22, at 18–24; FADEN & BEAUCHAMP, *supra* note 17, at 91–98.

24. BERG ET AL., *supra* note 22, at 18–20.

25. *See, e.g.*, GA. CODE ANN. § 31-9-6.1 (2018) (requiring disclosure of (1) diagnosis; (2) the proposed procedure's "nature and purpose"; (3) the material risks of "infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death"; (4) the procedure's likelihood of success; (5) alternative treatments; (6) prognosis if the proposed treatment is rejected); N.Y. PUB. HEALTH LAW § 2805-d (McKinney 2018) (requiring disclosure of "alternatives'' and "reasonably foreseeable risks and benefits"); 40 PA. CONS. STAT. ANN. § 1303.504 (West 2018) (requiring "a description of a procedure" as well as disclosure of "risks and alternatives"); TEX. CIV. PRAC. & REM. CODE ANN. §§ 74.101, 74.104 (West 2018) (requiring disclosure of the "risks or hazards" involved in a procedure).

26. *See, e.g.*, Benjamin Moulton & Jaime S. King, *Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice*, 38 J. L. MED. & ETHICS 85, 85 (2010); Quill & Brody, *supra* note 19, at 764.

interests.[27] But these concerns, however well-founded, have not undermined the validity of the legal doctrine of informed consent, nor the importance of autonomy as a fundamental principle of medical ethics.

B. Patients as Consumers

The phrase "health care consumerism" is used to describe a variety of phenomena relating to patients' increasingly active role in their medical care. For the purposes of this Article, however, the most relevant aspect of health care consumerism is patients' desire to actively participate in treatment decisions. This desire has led to patients independently researching treatment options, requesting specific treatments that best satisfy their personal preferences, and seeking out providers willing to offer these treatments.

Sociologists in the 1970s first recognized the trend towards consumerism in health care.[28] Whereas the relationship between physician and patient was traditionally a power relationship grounded in deference to medical authority and expertise, patients' attitudes began to change, "shift[ing] away from patient-as-supplicant to patient-as-skeptic."[29] Armed with newfound societal recognition of the value of individual autonomy, patients became more willing to challenge physicians' authority.[30] Indeed, the changing language used to describe

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27. *See, e.g.*, JOE ALPER, ROUNDTABLE ON HEALTH LITERACY, BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE, AND INST. OF MED., INFORMED CONSENT AND HEALTH LITERACY: WORKSHOP SUMMARY (2015) (discussing how low health literacy impacts the efficacy of the informed consent process); Wendy Netter Epstein, *Nudging Patient Decision-Making*, 92 WASH. L. REV. 1255 (2017) (arguing that, compared to pure deference to patient autonomy, incorporating "nudges" into the medical decision-making process leads to better patient decisions); Jay Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, 139 (1977) (describing the legal doctrine of informed consent as a "symbol" which "has had little impact on patients' decision-making, either in legal theory or medical practice"); Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice,* 28 LEG. MED. 91, 99–101 (2007) (providing an overview of critiques of informed consent in action); Schuck, *supra* note 4, at 903–04 (describing the gap between the ideals of informed consent doctrine and its practical effect).

28. *See, e.g.*, Marie R. Haug & Bebe Lavin, *Public Challenge of Physician Authority*, 17 MED. CARE 844, 844 (1979); Leo G. Reeder, *The Patient-Client as a Consumer: Some Observations on the Changing Professional-Client Relationship*, J. HEALTH & SOC. BEHAV. 406, 406 (1972).

29. Clare Louise Stacey et al., *Demanding Patient or Demanding Encounter?: A Case Study of a Cancer Clinic*, 69 SOC. SCI. & MED. 729, 730 (2009); *see also* Marie R. Haug & Bebe Lavin, *Practitioner or Patient—Who's in Charge?*, J. HEALTH & SOC. BEHAV. 212, 212 (1981) (describing models of professional power in health care).

30. Haug & Lavin, *Public Challenge of Physician Authority*, *supra* note 28 (finding that substantial proportions of patients are willing to challenge physician authority); Haug & Lavin,

patients—now "consumers" of health care—reflected these changing societal roles.[31] As Leo Reeder wrote in an influential 1972 article describing the consumerist phenomenon in health care:

> As a client[,] . . . the individual delivers himself into the hands of the professional—who presumably is the sole decision-maker regarding the nature of the services to be delivered. On the other hand, when the individual is viewed as a consumer, he is a purchaser of services and tends to be guided by *caveat emptor*.[32]

These changes were—and continue to be—facilitated by greater public access to information about health and health care. Given that the traditional power relationship between doctor and patient was justified in part due to physicians' monopoly on medical knowledge, anything that bridged this knowledge gap contributed to the weakening of physicians' authority.[33] From the "do-it-yourself health books" of the 1970s and 1980s,[34] to the internet boom of the 1990s and 2000s,[35] to the rise of direct to consumer drug advertising,[36] patients have gradually developed

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Practitioner or Patient—Who's in Charge?, *supra* note 29, at 212 (finding that substantial proportions of both physicians and patients "express beliefs and report actions congruent with [a] consumerist perspective"); Quill & Brody, *supra* note 19, at 764 ("The consumer movement has taught patients to be more assertive, to question physicians' recommendations, and to demand interventions that might otherwise be withheld.").

31. Reeder, *supra* note 28, at 408.

32. *Id.* at 409 (emphasis in original); *see also* Haug & Lavin, *Practitioner or Patient—Who's in Charge?*, *supra* note 29, at 213 ("Caveat emptor, 'let the buyer beware,' rather than trust in the seller's goodwill, characterizes the transaction.").

33. Haug & Lavin, *Public Challenge of Physician Authority*, *supra* note 28, at 846, 850 (finding that health knowledge and education leads to attitudes challenging physician authority); Haug & Lavin, *Practitioner or Patient—Who's in Charge?*, *supra* note 29, at 212 (noting that the power relationship between doctor and patient is based in part on "the profession's monopoly on knowledge not easily accessible to the public").

34. Haug & Lavin, *Public Challenge of Physician Authority*, *supra* note 28, at 844; Haug & Lavin, *Practitioner or Patient—Who's in Charge?*, *supra* note 29, at 213.

35. Thomas L. Hafemeister & Richard M. Gulbrandsen, *The Fiduciary Obligation of Physicians to 'Just Say No' if an 'Informed' Patient Demands Services that Are Not Medically Indicated*, 39 SETON HALL L. REV. 335, at 346–49 (2009) (discussing research about patient internet use); Stacey et al., *supra* note 29, at 731 (summarizing research about the challenges associated with internet-informed patients); *id.* at 734 (noting that "demanding" patient encounters "generally resulted when patients used knowledge gleaned on the internet to push for particular treatments or therapies").

36. Hafemeister & Gulbrandsen, *supra* note 35, at 352–61 (discussing impact of direct to consumer advertising on patient requests and prescribing practices); Mark Peyrot et al., *Direct-to-Consumer Ads Can Influence Behavior*, 18 MKTG. HEALTH SERVS. 27 (1998) (analyzing factors associated with consumer prescription drug knowledge and requests); Mary Beth Pinto et al., *The Impact of Pharmaceutical Direct Advertising: Opportunities and Obstructions*, 15 HEALTH MKTG. Q. 89 (1998) (discussing benefits and drawbacks of direct to consumer advertising, including impact on patients and providers); Stacey et al., *supra* note 29, at 730 ("'Patients'' roles as consumers are reinforced in several ways, including direct-to-consumer advertising by drug companies.").

the ability to collect information and investigate medical options without relying on physician expertise.

Changes in modern medicine also contributed to this trend. As new treatments for common conditions developed, patients' options expanded. Rather than being limited to a single viable treatment option, today's patients are often offered a variety of approaches for managing and treating their illnesses. How these patients choose to proceed often has as much to do with their personal values and preferences—balancing quality of life issues against the possibility of extending life, for example—as with the clinical efficacy of the various treatment options.[37]

The practical result of these societal changes is that today's patients are more assertive[38] in voicing their concerns and more persistent[39] in seeking out the care that satisfies their personal preferences. Rather than deferring to physicians' recommendations, patients view the physician-patient encounter as an opportunity for bargaining and negotiation.[40]

Research indicates that many patients enter the physician-patient encounter with "specific expectations for care."[41] For example, patients may request prescription drugs that they learned about through direct-to-consumer advertising;[42] ask for antibiotics in situations when they are

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37. *See generally* Ronald M. Epstein & Ellen Peters, *Beyond Information: Exploring Patients' Preferences*, 302 JAMA 195 (2009) (discussing how patients construct preferences when several treatment options exist); Wennberg, *supra* note 11 (describing the phenomenon of preference-sensitive care).

38. Quill & Brody, *supra* note 19 ("The consumer movement has taught patients to be more assertive, to question physicians' recommendations, and to demand interventions that might otherwise be withheld.").

39. Drew Foster, *'Keep Complaining til Someone Listens': Exchanges of Tacit Healthcare Knowledge in Online Illness Communities*, 166 SOC. SCI. & MED. 25, 25 (2016) (finding that online patient communities serve as forums in which patients can learn how to "receive their desired form of care from the health system and to negotiate relationships with medical professionals and institutions," and that these communities view persistence is a necessary strategy when seeking out high-quality medical care).

40. Haug & Lavin, *Practitioner or Patient—Who's in Charge?*, *supra* note 29, at 213; Richard L. Kravitz et al., *Characterizing Patient Requests and Physician Responses in Office Practice*, 37 HEALTH SVCS. RES. 215, 216 (2002); Reeder, *supra* note 28, at 409.

41. Stacey et al., *supra* note 29, at 732; *see also* Kravitz et al*., infra* note 45, at 1673 (finding that 23% of patients, in an observational study of patient visits to physicians, requested at least one test, new prescription, or referral); *cf.* B. Mitchell Peck et al., *Do Unmet Expectations for Specific Tests, Referrals, and New Medications Reduce Patients' Satisfaction?*, 19 J. GEN. INTERNAL MED. 1080, 1082, 1085 (2004) (finding that 56% of patients seeing their primary care providers have at least one "expectation for a test, referral, or new medication," but that many of these expectations are "vague").

42. Nicky Britten & Obioha Ukoumunne, *The Influence of Patients' Hopes of Receiving a Prescription on Doctors' Perceptions and the Decision to Prescribe*, 315 BMJ: BRITISH MED. J. 7121 (1997) (finding, in a survey of over 500 patients waiting to see their general practitioners, that 67% hoped for a prescription); Benjamin Lewin, *Patient Satisfaction with Physician Responses*

not appropriate,[43] or request specific diagnostic tests or referrals.[44] When their expectations are not met, patients are more likely to be dissatisfied with their medical care.[45] If they have the freedom to do so, patients may choose to "shop around" to find providers who are willing to comply with their requests.[46]

Perhaps not surprisingly, these consumerist trends have impacted medical practice. One author described "fulfillment of patient

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During Interactions Prompted by Pharmaceutical Advertisements, 50 SOC. SCI. J. 491 (2013) (finding that direct-to-consumer drug advertising shapes patients' expectations and leads patients to mention or request specific drugs to their physicians). Many physicians have negative views of patient demands for prescription medication, in part because they believe these demands are based on incorrect information or unreasonable expectations. Peyrot et al., *supra* note 36, at 28 ("Often physicians view advertising as a challenge to medical authority, and fear that patients will make inappropriate drug requests."); *id.* at 94 ("Advertising that is intended to increase the demand for drugs is also likely to increase the number of people making incorrect assumptions about the appropriateness of these medications. When patients demand specific prescriptions, they may collide with physicians more knowledgeable about the efficacy of the drug in question."); Woodie M. Zachry III et al., *Clinicians' Responses to Direct-to-Consumer Advertising of Prescription Medications*, 163 ARCHIVES INTERNAL MED. 1808, 1808 (2003) (finding that physicians are more likely to become "annoyed' and "frustrated" when patients ask about medications they learned about through direct-to-consumer drug advertising than through other sources of information).

43. Tanya Stivers, *Participating in Decisions about Treatment: Overt Parent Pressure for Antibiotic Medication in Pediatric Encounters*, 54 SOC. SCI. & MED. 1111, 1111 (2002) (summarizing research finding that pediatric physicians prescribe antibiotics as a result of parental insistence, even when their appropriateness is questionable).

44. Kravitz et al., *supra* note 40, at 229; Richard L. Kravitz, *Measuring Patients' Expectations and Requests*, 134 ANNALS INTERNAL MED. 881, 884 (2001); Jerry Menikoff, *Demanded Medical Care*, 30 ARIZ. ST. L.J. 1091, 1098 (1998).

45. *See* Robert A. Bell et al., *Unmet Expectations for Care and the Patient-Physician Relationship*, 17 J. GEN. INTERNAL MED. 817, 820 (2002) (finding that patients who held unmet expectations for care were less satisfied); Richard L. Kravitz et al., *Direct Observation of Requests for Clinical Services in Office Practice: What Do Patients Want and Do They Get It?*, 163 ARCHIVES INTERNAL MED. 1673, 1678 (2003) (finding that patient satisfaction was significantly decreased when a physician failed to fulfill an "action request" by a patient); Lewin, *supra* note 42 (finding that patients who mention a specific drug to their physicians and do not receive a prescription for that drug are less likely to be satisfied). *But see* Peck, *supra* note 41, at 1080–81, 84–85 (discussing research related to patient expectations and satisfaction but ultimately finding "little support for the relationship between fulfillment of specific expectations and patient satisfaction").

46. Stacey et al., *supra* note 29, at 730; *see also* Kristin K. Barker, *Electronic Support Groups, Patient-Consumers, and Medicalization: The Case of Contested Illness*, 49 J. HEALTH & SOC. BEHAV. 20, 20 (2008) (finding that participants "empower each other to search for physicians who will recognize and treat their condition accordingly"); Haug & Lavin, *Practitioner or Patient—Who's in Charge?*, *supra* note 29, at 214; *Drug Advertising Prompts Patient Discussion with Physicians, Study Shows*, HEALTH CARE STRATEGIC MGMT., at 7 (Sept. 1, 1999) (describing doctor shopping phenomenon); *cf.* Haug & Lavin, *Practitioner or Patient—Who's in Charge?*, *supra* note 29, at 233 (recognizing that some patients may not have the economic flexibility to change providers).

expectations" as "a major—if not *the* major—concern for clinicians."[47] Indeed, research indicates that when patients make requests or have specific expectations, physicians are more likely to comply than when patients don't have such expectations.[48] A 2003 study, for example, showed that physicians are more likely to provide a referral or new prescription to a patient who makes such a request.[49] A 1997 study found that physicians are more likely to prescribe medications when they believe that their patients expect a prescription,[50] even if it is not medically indicated.[51]

When physicians express frustration with "difficult" or "demanding" patients, they are often responding directly to patients' consumerist attitudes and expectations.[52] Some physicians now believe that their best safeguard against patient dissatisfaction is offering patients a "cafeteria"

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47. Peck, *supra* note 41, at 1080; *see also* Kravitz, *supra* note 44, at 881 (finding that meeting patient expectations, and in turn, increasing patient satisfaction, is correlated with "a lower propensity to sue for malpractice"); Zachry et al., *supra* note 42, at 1811 (noting that patient expectations for drug treatment may place pressure on physicians to meet those expectations).

48. Kravitz et al., *supra* note 45, at 1680 ("It is perhaps unrealistic to expect that physicians will refuse to provide clinical services to patients whose requests are sufficiently strident."); Kravitz, *supra* note 44, at 881 ("By acceding to the patient's request, the physician avoided a confrontation with the patient but left herself vulnerable to the disapproval of her colleagues.").

49. Kravitz et al., *supra* note 45.

50. Jill Cockburn & Sabrina Pit, *Prescribing Behaviour in Clinical Practice: Patients' Expectations and Doctors' Perceptions of Patients' Expectations*, 315 BRITISH MED. J. 520, 520 (1997) (finding that patients who expected a prescription were almost three times more likely to receive it than patients who came in without such expectations, and that physicians who thought their patient had such expectations were ten times more likely to prescribe).

51. Britten & Ukoumunne, *supra* note 42, at 1506 (finding that 22% of prescriptions written were "not strictly indicated on purely medical grounds"); Keerthi Gogineni et al., *Patient Demands and Requests for Cancer Tests and Treatments*, 1 JAMA ONCOLOGY 33, 35–36 (2015) (identifying "clinically inappropriate" patient requests as including requests for imaging studies, palliative treatments, and laboratory tests); Quill & Brody, *supra* note 19 (noting that "[t]he consumer movement has taught patients to . . . demand interventions that might otherwise be withheld"); Stivers, *supra* note 43, at 1127 (finding that parental pressure for antibiotics "can push physicians to prescribe antibiotics even when their appropriateness is questionable").

52. Bell et al., *supra* note 45, at 820 (finding that "visits in which patients reported an unmet expectation were perceived by physicians as being more demanding and less satisfying"); Kravitz et al., *supra* note 45, at 1680 ("Physicians experienced visits in which patients requested diagnostic tests as particularly demanding."); Kravitz, et al., *supra* note 40, at 217 (noting that patient requests for diagnostic tests, medications, and referrals "may foment patient-physician discord or distrust if not handled properly."); Stacey et al., *supra* note 29, at 729 (noting that "demanding" patient encounters "tend to happen when patients directly or indirectly challenge physician judgment, authority or jurisdiction," often as a result of consumerist tendencies or internet research); Zachry et al., *supra* note 42 (finding that physicians are likely to become "annoyed" and "frustrated" when patients ask about medications they learned about through direct-to-consumer drug advertising).

of options from which to choose—even if that is at odds with their own perceptions about best medical practice.[53]

The fact that some patients' expectations and requests for care do not align with best practices in medical care is particularly problematic. As noted above, many physicians report that patients regularly request unnecessary diagnostic tests and prescriptions—but providing these services, while professionally questionable, is unlikely to cause most patients significant harm. An unnecessary diagnostic test may result in a false positive, causing a patient anxiety about a medical condition she does not have; taking an unnecessary prescription may cause side effects that she could otherwise have avoided—but as a general matter, the risk of harm to patients from such accommodations is limited.[54]

That said, some patients seek out treatments that fall at the boundaries of responsible medical practice despite the significant medical risks of doing so. Section II.C.1, for instance, describes lawsuits by cancer patients who chose to forgo traditional treatments like chemotherapy and radiation that could have saved their lives, and instead sought out physicians offering alternative therapies that juries concluded were outside the standard of care. Another example can be found in parents skeptical of childhood vaccination, who often seek out "alternative vaccine schedules" that put their children (and others) at risk of infectious disease.[55] Physicians often comply with these requests,[56]

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53. Quill & Brody, *supra* note 19, at 764 ("Many physicians feel that giving patients the full range of choices and withholding their own recommendations are safeguards against lawsuits."); *cf.* Alan Meisel & Mark Kuczewski, *Legal and Ethical Myths about Informed Consent*, 156 ARCHIVES INTERNAL MED. 2521, 2523 (1996) (challenging the myth that the legal doctrine of "informed consent requires physicians to operate a medical cafeteria, in which they must set out all the therapeutic options and let patients choose, each according to his or her own appetite").

54. Note, however, that the provision of such unnecessary care may cause harms at societal level, by contributing to the rising costs of health care and, in turn, insurance premiums and government expenditures. Nadia N. Sawicki, *Informed Consent and Societal Stewardship*, 45 J. L. MED. & ETHICS 41, at 43–44 (2017) (patient choices may also have significant public health consequences, as in the case of non-vaccination); Wendy Netter Epstein, *The Health Insurer Nudge*, 91 S. CAL. L. REV. (forthcoming 2018), https://ssrn.com/abstract=3009823 [https://perma.cc/RL76-GJXC]; *see also* Lisa A. Newman, *Contralateral Prophylactic Mastectomy: Is It a Reasonable Option?*, 312 JAMA 895, 896 (2014) (considering whether medically unnecessary contralateral prophylactic mastectomies are an "unjustified expense" in an era of scarce health care resources).

55. Paul A. Offit & Charlotte A. Moser, *The Problem with Dr Bob's Alternative Vaccine Schedule*, 123 PEDIATRICS e164, e164 (2009); *see also* Allison Kempe et al., *Physician Response to Parental Requests to Spread out the Recommended Vaccine Schedule*, 135 PEDIATRICS 666, 666 (2015) (finding that 93% of pediatricians and family physicians surveyed reported parents making such requests in an average month); *Vaccine Schedule: Altering the Schedule*, CHILDREN'S HOSP. PHILA., http://www.chop.edu/centers-programs/vaccine-education-center/vaccine-schedule/altering-the-schedule [https://perma.cc/G2NA-7CJM] (noting that "some parents now feel they should

despite the fact that these alternative approaches have been described by experts as being based on "bad science."[57] Some authors believe that doctors who allow their patients to negotiate childhood vaccination "flirt[] with malpractice."[58]

Many other alternative and experimental therapies are risky not only because they are sought out in lieu of traditional therapies with proven success, but also because they pose significant independent risks of their own. For example, a variety of alternative treatments of questionable efficacy are marketed to parents of children with autism spectrum disorder, many of whom choose to pursue complementary and alternative therapies.[59] While some of these alternative treatments pose no safety risks,[60] others can be quite harmful.[61] Chelation therapy, for example, was originally developed as a treatment for lead toxicity, and is used to remove essential minerals from the bloodstream.[62] However, when used in children who do not have lead poisoning, chelation therapy can lead to cognitive impairments and even fatalities; its use resulted in

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approach the childhood immunization schedule in an a la carte manner, giving their children only those vaccines that they feel are appropriate").

56. Kempe et al., *supra* note 55, at 669–70 (finding that 37% of pediatricians and family physicians "often" or "always" agreed to delay vaccines at a parent's request, and 37% "sometimes" agreed to do so).

57. Offit & Moser, *supra* note 55.

58. Jim Anderson, *Are Immunization Schedules Negotiable?*, CLINICAL ADVISOR (Oct. 22, 2015), http://www.clinicaladvisor.com/the-waiting-room/are-immunization-schedules-negotiable/article/448840/ [https://perma.cc/U98K-W6GL].

59. According to some studies, somewhere between 52% and 95% of parents of children with autism now seek out complementary and alternative therapies. R. Scott Akins, Kathy Angkustsiri & Robin L. Hansen, *Complementary and Alternative Medicine in Autism: An Evidence-Based Approach to Negotiating Safe and Efficacious Interventions with Families*, 7 NEUROTHERAPEUTICS 307, 308 (2010).

60. *Id.* (citing music therapy, yoga, vitamins, dietary changes, essential fatty acids, amino acids, craniosacral manipulation, acupuncture, massage, and others as examples of safe interventions with unknown efficacy or no efficacy).

61. *Id.* (citing chelation therapy, antifungal agents, hyperbaric oxygen therapy, and immune therapies as examples of interventions that are unsafe or whose safety is unknown, and whose use should be discouraged); *see also* Alisa Opar, *The Dangers of Snake-Oil Treatments for Autism*, ATLANTIC (Sept. 22 2016), https://www.theatlantic.com/health/archive/2016/09/fringe-therapies-spectrum/501023/ [https://perma.cc/42TN-CVFB] (describing various dangerous treatments sought out by parents of children with autism, including chelation, hyperbaric oxygen therapy, ingestion of chemicals, and others); Trine Tsouderos & Patricia Callahan, *Risky Alternative Therapies for Autism Have Little Basis in Science*, CHI. TRIB. (Nov. 22, 2009), http://www.chicagotribune.com/lifestyles/health/chi-autism-treatments-nov22-story.html [https://perma.cc/Y9CM-JXZB].

62. Akins et al., *supra* note 59, at 312.

three deaths between 2003 and 2005, and the FDA has recently issued a warning about the use of chelation therapy for autism.[63]

Finally, some patients seek out treatments that have been clearly rejected by the U.S. medical community as falling outside the standard of care. Sexual orientation conversion therapy (SOCE), for example, is viewed by the majority of health care providers as ineffective and unethical, and its use has been challenged by most professional regulatory bodies.[64] Many states have recently passed legislation barring health care providers from offering such therapy (at least to minors).[65] And despite research demonstrating that many patients suffer significant harms as a result of SOCE—ranging from loss of self-esteem to sexual dysfunction to suicide[66]—patients continue to seek it out, resulting in ethical challenges for providers who believe that such therapy violates professional standards.[67]

Another, more striking example of a patient-requested service that has been roundly rejected by the medical community is when patients suffering from body dysmorphic disorder or apotemnophilia seek out physicians willing to amputate healthy limbs.[68] Doctors abroad have

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63. *Id.*; *Autism: Beware of Potentially Dangerous Therapies and Products*, U.S. FOOD & DRUG ADMIN. (Apr. 12, 2017), https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm394757.htm [https://perma.cc/6ER2-DN9G].

64. *See* Douglas C. Haldeman, *Gay Rights, Patient Rights: The Implications of Sexual Orientation Conversion Therapy*, 33 PROF'L PSYCHOL. 260, 260 (2002); Jon S. Lasser & Michael C. Gottlieb, *Treating Patients Distressed Regarding Their Sexual Orientation: Clinical and Ethical Alternatives*, 35 PROF'L PSYCHOL.: RES. & PRAC. 194, 194 (2004); Michael Schroeder & Ariel Shidlo, *Ethical Issues in Sexual Orientation Conversion Therapies: An Empirical Study of Consumers*, 5 J. GAY & LESBIAN PSYCHOTHERAPY 131, 131 (2008).

65. King v. Governor of N.J., 767 F.3d 216 (3d Cir. 2014) (upholding New Jersey ban on conversion therapy); Pickup v. Brown, 740 F.3d 1208, 1236 (9th Cir. 2014) (upholding California ban on conversion therapy for children); *see also* D.C. CODE § 7-1231.14a (2015) (prohibiting mental health professionals from engaging in sexual orientation change efforts with minors); 405 ILL. COMP. STAT. ANN. 48/30 (2016) (same); H.B. 2307, 78th Leg. Assemb., Reg. Sess. (Or. 2015).

66. *See* Douglas C. Haldeman, *Therapeutic Antidotes: Helping Gay and Bisexual Men Recover from Conversion Therapies*, 5 J. GAY & LESBIAN PSYCHOTHERAPY 117, 117 (2002); Ariel Shidlo & Michael Schroeder, *Changing Sexual Orientation: A Consumer's Report*, 33 PROF'L PSYCHOL. 249, at 254–55 (2002).

67. *See* Lasser & Gottleib, *supra* note 64; Haldeman, *supra* note 64; Schroeder & Shidlo, *supra* note 64.

68. Annemarie Bridy, *Confounding Extremities: Surgery at the Medico-Ethical Limits of Self-Modification*, 32 J. L. MED. & ETHICS 148, 148 (2004); Aimee Louise Bryant, *Consent, Autonomy, and the Benefits of Healthy Limb Amputation: Examining the Legality of Surgically Managing Body Integrity Identity Disorder in New Zealand*, 8 J. BIOETHICAL INQUIRY 281, 281 (2011); Josephine Johnston & Carl Elliott, *Healthy Limb Amputation: Ethical and Legal Aspects*, 2 CLINICAL MED. 431, 431 (2002).

been willing to perform such surgeries at a patient's request,[69] arguing that it is both ethically appropriate and therapeutically valuable to patients who would otherwise live with "a desire so obsessive that it leads to thoughts of suicide."[70] But there is no indication that U.S. physicians are willing to do so, in part because of professional opposition to the practice,[71] and in part because of the significant risk of liability.[72]

While some of these examples seem extreme, they are offered to demonstrate the range of services that patient-consumers seek out from the medical community. Medical services that are not universally accepted as being within the standard of care fall on a broad spectrum, ranging from services that are accepted by a substantial minority of physicians (which, depending on a state's medical malpractice law, may fall within the standard of care), to services that are supported by evidence but are not customarily offered by physicians because of liability concerns,[73] to services that clearly fall outside the scope of responsible medical practice and are almost uniformly rejected.

When patients suffer injury as a result of these treatments and ultimately seek recovery, the final decision about whether a treatment falls outside the standard of care is typically made by a jury. To make this determination, jurors certainly look to the testimony of expert witnesses, but they also imbue their decisions with their own value

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69. *See* Clare Dyer, *Surgeon Amputated Healthy Limbs*, 320 BMJ: BRITISH MED. J. 7231, 7231 (2000).

70. Johnston & Elliott, *supra* note 68, at 432; *see also* Bridy, *supra* note 68, at 153 ("The issue is made particularly difficult by the conceptual chasm between people . . . who in their best clinical judgment believe that elective amputation *can* be therapeutically beneficial, and people . . . who express an automatic but principled conviction that the surgery has no therapeutic value and represents a *per se* violation of medical ethics." (emphasis added)).

71. *See* Jason Beckford-Ball, *The Amputation of Healthy Limbs Is Not an Option*, 9 BRITISH J. NURSING 188, 188 (2000) (arguing that health care professionals should not "collude with people's distorted body image" and "legitimize self-harm" by amputating healthy limbs); Randy Dotinga, *Out on a Limb*, SALON (Aug. 29, 2000, 12:00 PM), https://www.salon.com/2000/08/29/amputation/ [https://perma.cc/KE6N-Q5FE] (quoting medical ethicist Arthur Caplan describing medical amputation of healthy limbs as a violation of the Hippocratic Oath and as "absolute, utter lunacy"); Johnston & Elliott, *supra* note 68 (concluding that ethical concerns stand in the way of professional acceptance of healthy limb amputation).

72. Johnston & Elliott, *supra* note 68, at 432 (noting that "a court might consider a healthy limb amputation . . . to be negligent because the procedure is not yet considered by a responsible body of medical opinion to be an appropriate and effective treatment of a medical condition").

73. A well-recognized problem with the fact that the standard of care in medicine is defined by professional custom is that the adoption of changes—even very beneficial ones—is slow. Evidence may support a new treatment option, but physicians may be unwilling to adopt it if their colleagues have not done so because without such widespread adoption a jury could not find that the new treatment was customary within the community. *See infra* note 284.

judgments—about whether the plaintiff or the defendant is more reliable, about what they would want their own physicians to do, and about whether injured plaintiffs are deserving of compensation at all. It is possible that a jury may impose liability on a physician for conduct that is generally accepted as being within the standard of care, simply due to the testimony of a sympathetic plaintiff who has suffered serious injuries.

"Value judgments, then, are inherent in the determination of virtually any medical standard of care."[74] As a result, it can be challenging for physicians to predict where patient-requested care falls on the spectrum, whether complying with a patient's request for unorthodox treatment or denying it is more likely to subject them to malpractice liability. Thus, physicians make value judgments here too, balancing the likelihood of harm resulting from complying with a patient request with the likelihood of patient dissatisfaction or harm from denying it. Given that it can be difficult to predict whether a jury will view a physician's conduct as falling within the standard of care, the preparation of defenses, like assumption of risk and contractual waiver, becomes extremely important.

C. The Scholarly Debate: Contract, Tort, and Fiduciary Principles

The shift towards a consumerist and autonomy-based model of health care significantly impacted the practice of medicine. However, these changes also had implications beyond the realm of medical decision-making, prompting discussion in legal spheres about the common law's treatment of patients seeking legal recovery for medical malpractice.[75] Legal scholars highlighted a fundamental inconsistency between modern informed consent law's conception of patients as autonomous agents, and courts' ongoing reliance on a "vulnerable patient" narrative to support policy arguments barring enforcement of contractual waivers of liability.[76]

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74. Menikoff, *supra* note 44, at 1108.

75. Richard A. Epstein, *Medical Malpractice: The Case for Contract*, 1 L. & SOC. INQUIRY 87, 126–27 (1976) (describing freedom of contract as "an outgrowth of the principle of personal autonomy"); Maxwell J. Mehlman, *The Patient-Physician Relationship in an Era of Scarce Resources: Is There a Duty to Treat?*, 25 CONN. L. REV. 349, 355 (1992) ("A contractual approach to the patient-physician relationship is also suggested by . . . the movement to increase patient autonomy.").

76. Epstein, *supra* note 75, at 127 (arguing that the view that patients are "incompetent to fend for themselves" is inconsistent with the lengths the law goes to in ensuring that patients are well-informed); *see also* Laakmann, *supra* note 8, at 933 (noting that court's "hostil[ity] to the defense of implied assumption of risk . . . subtly undermines the rationale behind the informed consent

Scholars began to consider whether, just as patients are better served by making autonomous health care choices rather than deferring to the paternalistic choices of the medical profession, patients might likewise be better served if they had the opportunity to contract with their providers for terms that satisfy their preferences rather than be subject to the default rights and duties set by tort law.

This conversation was driven primarily by scholars of law and economics, who viewed contract law as a solution to the "medical malpractice crisis" of the 1980s.[77] They were responding to a legal regime in which courts were resistant to enforcing contractual modifications to health care providers' duties or patients' right to recovery.[78] The default liability rules set by tort law, these scholars argued, were too favorable to plaintiffs and therefore encouraged high malpractice payouts—leading to increased malpractice insurance premiums, increased costs to patients, and physicians leaving the practice of medicine.[79] In their view, not only was the tort regime unfavorable to defendant physicians, but it also imposed costs on patients who might not want or need the protection of tort law.[80] Changing the medical malpractice system, they argued, would be a natural extension of recent changes in health care delivery and financing.[81]

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doctrine, as it implies that patients are summarily incapable of making rational choices about uncertain treatments"); Glen O. Robinson, *Rethinking the Allocation of Medical Malpractice Risks Between Patients and Providers*, 49 L. & CONTEMP. PROBS. 173, 193 (1986) ("[T]he assumption of patient ignorance is at odds with the trend toward greater physician disclosure as a prerequisite of informed consent, which is premised on a new appreciation of the value of patient autonomy and responsibility in making choices about health care.").

77. A full issue of the 1986 volume of *Law and Contemporary Problems* was dedicated to addressing this problem. 49 L. & CONTEMP. PROBS. 2 (1986).

78. *See infra* section II.B.

79. Epstein, *supra* note 75, at 87–89.

80. Much of the discussion surrounding contractual modifications to physicians' tort law duties centered around the need for cost containment and the hypothetical "cost-conscious patient." *See* Clark C. Havighurst, *Private Reform of Tort-Law Dogma: Market Opportunities and Legal Obstacles*, 49 L. & CONTEMP. PROBS. 143, 149 (1986) [hereinafter Havighurst, *Private Reform of Tort-Law Dogma*] ("[I]f some consumers are demanding economy, a strong argument can be made for allowing a provider's legal obligations to vary so that a less costly product can be delivered in response to that demand."); Clark C. Havighurst, *Altering the Applicable Standard of Care*, 49 L. & CONTEMP. PROBS. 265, 275 (1986) [hereinafter Havighurst, *Standard of Care*] ("[C]onsumers should not be deprived by law of their freedom to opt for fewer costly legal rights than the legal monopoly seeks to confer upon them.").

81. Epstein, *supra* note 4, at 201 (arguing that the transformation of the health care delivery system should provide guidance in the context of medical malpractice reform); Havighurst, *Private Reform of Tort-Law Dogma*, *supra* note 80, at 143 ("[P]rivate reform in the area of medical malpractice squares nicely both with recent developments in national health policy and with recent

The primary argument made by this school was that it would be more efficient if patients and providers could freely contract to set the terms of their relationships and the consequences of non-performance, rather than having standards of care and liability rules imposed upon them by the tort law system. They argued that the traditional barriers to efficient contracting—lack of choice[82] and lack of information[83]—were either disappearing in the modern health care environment, or could be easily overcome.[84] Scholars further supported this economic argument by pointing to legal theory, arguing that the consensual relationship between doctor and patient more closely resembles commercial relationships governed by contract than the relationships between strangers typically governed by tort law.[85] The malpractice crisis, they argued, was simply evidence of the fact that tort law is an imperfect fit in this context.

The contractual terms that scholars believed should be negotiable between doctor and patient included terms relating to allocation of costs, size of recovery, arbitration, standards of care, no-fault compensation, collateral sources, periodic payments, punitive damages, proof of breach, and limitation of liability to gross negligence.[86] Of these, the most

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changes in the health care industry itself."); Robinson, *supra* note 76, at 180 (arguing that economic changes in the health care industry should cause us to rethink malpractice liability rules); *id.* at 198 (arguing that courts' paternalistic attitude in barring contractual modifications to liability rules "is out of touch with the reality of modern health care services").

82. Havighurst, *Private Reform of Tort-Law Dogma*, *supra* note 80, at 144 (identifying "the emergence of a competitive market for health services and new opportunities for informed purchasing by consumers" as a reason to support health care contracting); Robinson, *supra* note 76, at 186–87 (citing the prevalence of elective procedures and low-value care to support the argument that patients seeking medical care have the opportunity for reasonable deliberation among various options).

83. Epstein, *supra* note 4, at 202 (arguing that disclosure requirements could remedy the information gap between doctor and patient); Robinson, *supra* note 76, at 188–93 (dismissing arguments about patients' comparative lack of information as flawed).

84. Relatedly, some argued that concerns about barriers to efficient contracting are resolvable by having sophisticated agents like employers or insurers (rather than patients) engaging in negotiation of contract terms. *See* Epstein, *supra* note 4, at 210; William H. Ginsburg et al., *Contractual Revisions to Medical Malpractice Liability*, 49 L. & CONTEMP. PROBS. 253, 256 (1986); Havighurst, *Private Reform of Tort-Law Dogma*, *supra* note 80, at 168–69.

85. Epstein, *supra* note 4, at 211 (arguing that "there is nothing special, much less sacred, about medical services that justifies exempting them from ordinary contracting processes"); Robinson, *supra* note 76, at 182–83 (arguing that twentieth century efforts to professionalize medicine and distinguish it from commercial practice fail to recognize that "the provider/patient relationship is grounded in contract and most of the economic terms are set by the usual elements of contract formation").

86. *See* Havighurst, *Private Reform of Tort-Law Dogma*, *supra* note 80, at 161–62; Ginsburg et al., *supra* note 84, at 258–63.

challenging to defend were modifications of the customary standard of care[87] and complete waivers of liability,[88] both of which, according to some, pushed the boundaries of unconscionability.

Modern scholars have challenged the full freedom-of-contract view, and many have instead offered more nuanced approaches for ensuring that both patients and physicians can effectively satisfy their preferences. For example, some argue that applying pure contract principles in the health care context fails to take into account the fiduciary basis of the doctor-patient relationship, and that therefore contractual modifications ought to be subject to a set of standards that takes these fiduciary duties into account.[89] Others argue that resorting to contract law is unnecessary because tort law itself can provide a solution to the efficiency problems described by law and economics scholars.[90] For example, the tort defense of assumption of risk—like contractual waivers of liability, typically rejected by courts in medical malpractice cases—could serve to protect physicians while allowing patients to pursue their preferences.[91]

The scholarly debate about whether tort, fiduciary, or contract principles should govern medical liability continues to this day. Nevertheless, American common law has not kept pace.[92] As described

87. Epstein, *supra* note 75, at 103 (acknowledging that "the requirement of reasonable care, as elaborated in traditional negligence cases, is a fair implication of the terms on which the [doctor-patient] relationship is premised"); Havighurst, *Standard of Care*, *supra* note 80, at 270 (suggesting that courts may view agreements to modify the standard of care as violating public policy, but offering drafting suggestions for avoiding charges of unconscionability).

88. *See* Havighurst, *Private Reform of Tort-Law Dogma*, *supra* note 80, at 165 (noting that broad exculpatory clauses might be "too much for most courts to handle").

89. Maxwell Mehlman, for example, has proposed a model of "fiduciary contracting" to be used in the health care context, which would require proof that the conditions for efficient contracting—information and choice—have been satisfied. *See generally* Mehlman, *supra* note 7; *see also* Mark Hall, *The Legal and Historical Foundations of Patients as Medical Consumers*, 96 GEO. L.J. 583, 591–97 (2008) (noting that while health care law has "conventional contractual foundations," it also deviates from traditional contract principles in ways that reflect the unique relationship between health care provider and patient); Hall & Schneider, *supra* note 7, at 775 (noting that "fiduciary principles strongly influence how contract principles apply to medical decisions"); Laakmann, *supra* note 8, at 965–66 (arguing that in the medical context, "law should distinguish between non-negotiable fiduciary duties and duties that may be contractually modified by the parties"); Mehlman, *supra* note 7, at 366–67 (criticizing the Chicago school for neglecting to consider fiduciary aspects in their contracting arguments).

90. Jennifer Arlen, *Private Contractual Alternatives to Malpractice Liability*, *in* MEDICAL MALPRACTICE AND THE US HEALTH CARE SYSTEM 245, 257 (2006) (arguing that contract law solutions do not offer patients the same benefit as tort law); Patrick S. Atiyah, *Medical Malpractice and the Contract/Tort Boundary*, 49 L. & CONTEMP. PROBS. 287, 287 (1986) (arguing that the solution is to change tort law, not move to contract).

91. Nelson, *supra* note 4, at 791; *see generally* Laakmann, *supra* note 8.

92. Schuck, *supra* note 4, at 908 ("Tort law has largely eclipsed consent-contract approaches to the problem of health-care-related injuries.").

below, courts are still quite resistant to any attempt by providers to minimize their liability on the basis of a patient's voluntary agreement, or to modify the default rules of the doctor-patient relationship by way of contractual agreement.[93]

II. COMMON LAW APPROACHES TO PHYSICIAN LIABILITY

As described above, the shift towards a consumerist model of health care led some legal scholars to argue that, just as patient preferences now drive treatment decisions, those preferences should also drive the law's approach to recovery. Nevertheless, many courts continued to bar the use of both contract- and tort-based defenses based on a patient's decision to proceed with treatment under conditions agreed to with the provider. Under common law, physicians are expected to prioritize the interests of their patients and satisfy professional standards of care, and courts are generally unwilling to allow physicians to defend themselves in malpractice cases on the basis of a contractual agreement with the patient. So, too, are courts generally hostile to the tort defense of assumption of risk, which relieves a physician of liability if a patient voluntarily (but non-contractually) chooses to encounter a known risk.

This Part explains how contractual waivers of liability and the tort doctrine of assumption of risk can be used by health care providers to limit liability in medical malpractice actions, and describes courts' traditional resistance to the use of such defenses. It also provides a comprehensive overview of the many cases in which courts have been receptive to such defenses, setting the foundation for Part III's discussion of how the use of these defenses could be expanded to a broader variety of contexts.

A. Contract and Tort Defenses Based on Voluntary Acceptance of Risk

When a physician charged with malpractice wishes to defend himself on the grounds of a patient's voluntary acceptance of risk, he may rely on either contract- or tort-based defenses. If the patient has signed a waiver, release of liability, or covenant not to sue, the defendant physician may point to that contractual agreement in an attempt to bar suit. If there has been no explicit contractual agreement to relieve the physician from liability, the physician may be able to rely on the tort doctrine of assumption of risk to bar or reduce recovery if he can prove

93. *Id.* at 911–12.

that the patient voluntarily chose to encounter a known risk. Whether grounded in contract or in tort, both defenses are premised on a patient's voluntary choice to encounter a known risk.

1. Contractual Release of Liability

While tort law establishes a set of default principles defining general duties of care, contract law is the mechanism by which parties entering into an intentional relationship can define the scope of their duties more narrowly or more broadly. A contract may even release one party from the duty to exercise due care entirely,[94] leaving the second party with no remedy for some types of injuries.[95]

Contractual provisions that prospectively limit future liability for negligent conduct are strictly construed.[96] For such exculpatory clauses to be enforceable, their language must clearly and unambiguously describe the scope of the waiver of liability, such that the party waiving his rights is able to understand the rights he is giving up.[97] Even if these requirements are satisfied, however, a waiver may still be unenforceable if it violates public policy or affects the public interest,[98] which is particularly relevant in cases dealing with medical services.[99]

A defendant sued for negligence can therefore raise, as a defense, the plaintiff's contractual agreement to relieve him from liability for

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94. RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 2 cmt. c (AM. LAW INST. 2000) ("The essential element of a contractual limitation on liability is that each party agrees that the defendant is under no obligation to protect the plaintiff and shall not be liable to the plaintiff for the consequences of conduct that would otherwise be tortious.").

95. Such contractual provisions may be referred to as releases, waivers, covenants not to sue, or exculpatory clauses, depending on whether the parties are contracting about an existing claim or about future conduct. That said, there is widespread agreement that these terms are imprecise, often overlap, and are frequently misused. *See, e.g.*, 17A AM. JUR. 2d Contracts § 275 (2017) (noting the various terms used to describe contractual agreements to exempt one party from future liability to another); WILLIAM R. ANSON, PRINCIPLES OF THE LAW OF CONTRACT 419 (Arthur L. Corbin ed., 3d ed. 1919) ("The term *waiver* is one of those words of indefinite connotation in which our legal literature abounds; like a cloak, it covers a multitude of sins."). For reasons of simplicity, this Article will primarily use the term "waiver" to describe such prospective contractual waivers of liability.

96. 17A AM. JUR. 2d *Contracts* § 276; 8 WILLISTON ON CONTRACTS § 19:21 (4th ed. 2017); *see also* RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 2 cmt. d.

97. 8 WILLISTON ON CONTRACTS, *supra* note 96, §§ 19:21, 19:25.

98. RESTATEMENT (SECOND) OF CONTRACTS § 178 (AM. LAW INST. 1981); 8 WILLISTON ON CONTRACTS, *supra* note 96, §§ 19:22, 19:23; *see also* Tunkl v. Regents of Univ. of Cal., 383 P.2d 441 (Cal. 1963).

99. *See infra* section II.B.

negligent conduct. If this contractual agreement is deemed to be enforceable, the plaintiff's negligence claim will be dismissed.

2. Express Assumption of Risk

Express assumption of risk is a tort law defense that overlaps considerably with the contract defenses described above.[100] A plaintiff expressly assumes a risk when she explicitly (verbally or in writing) agrees to accept a known risk of harm arising from a defendant's conduct.[101] Like contractual waiver, express assumption of risk is commonly viewed as either an agreement to release the defendant from an existing duty of care,[102] or an agreement not to sue the defendant for injuries resulting from negligent conduct.[103] It is treated as a form of contract, and so is typically subject to the same requirements as the contractual limitations on liability described above.[104] The consequence of a finding of express assumption of risk is a complete bar on recovery by the plaintiff.[105]

3. Implied Assumption of Risk

Implied assumption of risk describes a scenario where a plaintiff's *conduct* (rather than her explicit verbal or written agreement) indicates that she is choosing to voluntarily encounter a known risk. In such cases,

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100. DAN B. DOBBS ET AL., THE LAW OF TORTS § 233 (2d ed. 2016) ("Any assumption of risk in its express form is a contract, and is thus subject to the laws of contract enforceability and interpretation."). That said, some courts appear to draw a distinction between contractual waivers and express assumption of risk, holding that express assumption of risk may be a viable defense even if the contractual waiver the plaintiff signed was unenforceable. *See, e.g.*, Poag v. Atkins, 806 N.Y.S.2d 448 (Sup. Ct. 2005) (describing an exculpatory clause contained in a consent form as invalid on policy grounds, but holding there was a genuine issue of material fact as to whether the patient expressly assumed the risks of medical treatment when she signed the consent form); Schneider v. Revici, 817 F.2d 987 (2d Cir. 1987) (finding that the covenant not to sue in a consent form signed by the patient was unenforceable due to lack of precision, but that the consent form constituted sufficient evidence to allow a jury to consider express assumption of risk as a defense).

101. RESTATEMENT (SECOND) OF TORTS § 496B (AM. LAW INST. 1965); RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 2; DOBBS ET AL., *supra* note 100, § 232.

102. DOBBS ET AL., *supra* note 100, § 232.

103. *Id.* § 233.

104. RESTATEMENT (SECOND) OF TORTS § 496B; RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 2; DOBBS ET AL., *supra* note 100, § 233.

105. RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 2 (also noting that express assumption of risk survives the adoption of comparative negligence).

the plaintiff's ability to recover in tort is limited, much in the same way as if the plaintiff were found comparatively negligent.[106]

Regrettably, many courts appear to struggle with the distinctions between the two categories of implied assumption of risk described below.[107] Commentators have described the doctrine of implied assumption of risk as "superfluous and unnecessarily confusing,"[108] Nevertheless, this Article continues to use the language of implied assumption of risk, in part because of the author's belief that this categorization is valuable,[109] and also because many of the judicial opinions discussed herein rely on the traditional definitions and categorizations of assumption of risk.

a. Primary

Primary implied assumption of risk—a complete bar to recovery—is best understood not as a defense, but rather as a failure of the plaintiff's prima facie case for negligence.[110] When a defendant raises this "defense," he typically argues that the plaintiff was injured not as a result of a breach of duty by the defendant, but as a result of a risk inherent in an activity the plaintiff voluntarily chose to participate in.[111]

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106. Many jurisdictions have officially "merged" the implied assumption of risk defense into comparative negligence. DOBBS ET AL., *supra* note 100, § 237. The Third Restatement of Torts has abandoned the doctrine as well. RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 2 cmt. i.

107. Dale L. Moore, *Please Watch Your Language: The Chronic Problem of Assumption of Risk*, 61 CATH. U. L. REV. 175, 184 (2011) ("[C]areless language pervades these opinions, revealing either ignorance of or indifference to the analytical nuances particularly important in [precedential cases].").

108. DOBBS ET AL., *supra* note 100, § 237.

109. For an excellent analysis of the value of these categorizations, see Kenneth W. Simons, *Reflections on Assumption of Risk*, 50 UCLA L. REV. 481 (2002).

110. RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 2 reporters' note cmt j; DOBBS ET AL., *supra* note 100, § 237 ("[A] plaintiff's apparent consent is . . . ample ground for concluding that the defendant's duty is limited or that the defendant is simply not negligent at all."). Some commentators describe primary implied assumption of risk cases as those in which the plaintiff has failed to show a breach of duty on the part of the defendant; others have suggested that primary implied assumption of risk can describe cases where a plaintiff's conduct effectively relieves the defendant of the duty to protect a plaintiff from the inherent risks of an activity. 3 STEIN ON PERSONAL INJURY DAMAGES § 14:14 (3d ed. 1997) (in describing implied primary assumption of risk, noting that "voluntarily entering into a relationship with the defendant, and being fully aware that the defendant will not be responsible for protecting him or her from known future risks, the plaintiff impliedly relieves the defendant of any duty and agrees to accept the consequences"); *cf.* Moore, *supra* note 107, at 188–89 (noting that primary assumption of risk does not *relieve* a defendant of a duty; rather, either the duty does not exist in the first place, or it was not breached).

111. Inherent risks are ones that "cannot be eliminated without altering the fundamental nature of the activity." Beninati v. Black Rock City, 96 Cal. Rptr. 3d 105, 109 (Ct. App. 2009) (affirming

The most common cases of primary assumption of risk involve plaintiffs who voluntarily choose to engage in inherently dangerous recreational activities (like skiing or skydiving) and suffer injuries caused by the risks inherent in those activities.

In the medical context, an example of primary implied assumption of risk would be a patient whose physician prescribes a medication and explains that its potential side effects include nausea and vomiting. If the patient takes the medication with knowledge of its risks and ultimately suffers nausea and vomiting, she can be described as having impliedly assumed the risk of side effects from the medication.[112] Unless she can demonstrate that her physician was negligent in prescribing the medication or in describing its side effects, she will not be able to recover damages if she suffers nausea or vomiting. In effect, the physician's satisfaction of his legal duty to obtain informed consent operates as a "defense" to any claim by the plaintiff that the physician should be liable for her injuries.[113]

b. Secondary

Secondary implied assumption of risk, in contrast, is a true defense, raised after a plaintiff has made credible allegations of a defendant's breach of duty. When a defendant raises this defense, he argues that although the plaintiff may have been injured as a result of the defendant's negligence, the plaintiff's recovery should be reduced because he was aware of the defendant's negligence and voluntarily chose to encounter it.[114]

Proving secondary assumption of risk can be quite challenging because it is uncommon to find a plaintiff who is fully aware of the risk arising from a defendant's breach, but who nevertheless chooses to

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summary judgment against promoters of the Burning Man festival when the plaintiff, an attendee, sued for negligence when he suffered serious burns after falling into the burning remnants of the Man). They generally do not include the risk of negligence by a defendant offering the activity, or other "extraneous risks that can be avoided with reasonable care." DOBBS ET AL., *supra* note 100, § 237.

112. Moore, *supra* note 107, at 193–95; *see also* Owens v. Silvia, 838 A.2d 881, 903 (R.I. 2003) (affirming trial court's decision to introduce a consent form into evidence to show that plaintiff assumed the risks of certain injuries inherent in a surgical procedure, and that those injuries were caused not by negligence but "because such injuries occurred as part of the normal risks of undergoing this type of surgery").

113. MARK A. HALL ET AL., HEALTH CARE LAW AND ETHICS 431–32 (8th ed. 2013).

114. *See infra* section IV.A.3 for further discussion regarding the nuances of this definition and the doctrinal uncertainty regarding what, precisely, the plaintiff must be aware of.

intentionally encounter that risk.[115] In the medical context, notably, many instances of malpractice are unpredictable and unanticipated; thus, it would be difficult to prove that a plaintiff, in advance of proceeding with a treatment, was aware that the treating physician was or would be negligent. One example of a case in which this defense might be successful would be if a patient freely consented to receiving treatment from a physician who was quite obviously intoxicated.[116] A second example—and one most relevant to the arguments raised in this Article—would be if a physician recommended a treatment that was outside the standard of care, and the patient nevertheless chose to pursue that treatment after being fully informed of its risks.[117]

B. The Traditional Patient-Protective View

Many courts reject such contract- and tort-based defenses on essentially paternalistic grounds. Indeed, the cases taking this view are so prominent—and so well represented in law school casebooks—that some commentators make the understandable mistake of believing that

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115. In most cases, such a choice would be unreasonable, which is exactly why many view secondary assumption of risk as simply another type of comparative negligence. *See* 3 STEIN ON PERSONAL INJURY DAMAGES, *supra* note 110, § 14:14 ("When the plaintiff unreasonably volunteers or chooses to encounter a known risk, he or she is assuming the risk in the secondary sense. This may result from plaintiff's voluntary acceptance of an unreasonable risk, or from failing to exercise reasonable care to protect himself or herself after accepting a reasonable risk."). This author believes, however, that treating secondary implied assumption of risk as equivalent to comparative negligence is misguided. Comparative negligence requires proof that a plaintiff unreasonably failed to take precautions against a foreseeable risk, and that this decision was the cause of the plaintiff's injuries. While many instances of secondary assumption of risk also involve a plaintiff's unreasonable acceptance of known risks, others may involve a perfectly reasonable decision to accept a known risk in which the plaintiff has no opportunity to take precautions. Such situations cannot be described as acts of comparative negligence on the part of the plaintiff. *See* Simons, *supra* note 109 (analyzing the merits of distinguishing between reasonable and unreasonable assumptions of risk).

116. *See, e.g.*, Champs v. Stone, 58 N.E.2d 803, 803 (Ohio Ct. App. 1944) (holding that a patient who consented to receiving injections from a physician whose "gross intoxication" was "apparent" was either contributorily negligent or assumed the risk of negligent care).

117. Surprisingly, Dobbs views such a case as a "no breach" example of primary assumption of risk. DOBBS ET AL., *supra* note 100, § 237 (describing an alternative therapy case as one where the physician "undoubtedly owes his patient a duty of reasonable care," but breaches no duty when he "administer[s] only the care to which the patient consented," and noting that "the physician would violate the patient's rights if he administered a traditional treatment after agreeing not to"); *id.* at § 232 (describing a Jehovah's Witness case as one where "the physician owed the patient a duty of care but in fact exercised the appropriate care under the circumstances," on the grounds that the physician "would violate the patient's rights if he administered transfusions after agreeing not to do so"). For an explanation of why this interpretation is problematic, see section II.C.2.

these cases represent the entirety of common law's treatment of this issue.

The classic case rejecting contractual releases from liability in the medical context is *Tunkl v. Regents of University of California*.[118] In *Tunkl*, a patient seeking admission to a charitable research hospital was asked, as a condition of admission, to sign a document purporting to release the hospital from liability for the negligent acts of its employees.[119] The California Supreme Court held that because an exculpatory agreement between a hospital and a patient affects the public interest, it is unenforceable on policy grounds.[120] The Court carefully analyzed a variety of elements relevant to the question of whether a contract affects the public interest,[121] and found that the hospital-patient contract clearly satisfies them. Courts in many jurisdictions have relied upon the reasoning set forth in *Tunkl* to conclude that health care providers, including physicians,[122] cannot contract their way out of liability for negligence.[123] Where no contractual release exists, and physician defendants instead rely on implied

118. 383 P.2d 441 (Cal. 1963).

119. *Id.* at 441.

120. *Id.* at 447.

121. A contract affecting the public interest, according to the *Tunkl* court, "exhibits some or all of the following characteristics":

> It concerns a business of a type generally thought suitable for public regulation. The party seeking exculpation is engaged in performing a service of great importance to the public, which is often a matter of practical necessity for some members of the public. The party holds himself out as willing to perform this service for any member of the public who seeks it, or at least for any member coming within certain established standards. As a result of the essential nature of the service, in the economic setting of the transaction, the party invoking exculpation possesses a decisive advantage of bargaining strength against any member of the public who seeks his services. In exercising a superior bargaining power the party confronts the public with a standardized adhesion contract of exculpation, and makes no provision whereby a purchaser may pay additional reasonable fees and obtain protection against negligence. Finally, as a result of the transaction, the person or property of the purchaser is placed under the control of the seller, subject to the risk of carelessness by the seller or his agents.

Id. at 445–46.

122. *See, e.g.*, Belshaw v. Feinstein, 65 Cal. Rptr. 788 (Ct. App. 1968) (extending *Tunkl's* public interest reasoning to contracts between patients and physicians).

123. *See, e.g.*, Porubiansky v. Emory Univ., 275 S.E.2d 163 (Ga. Ct. App. 1980), *aff'd*, 282 S.E.2d 903 (Ga. 1981); Meiman v. Rehab. Ctr., Inc., 444 S.W.2d 78 (Ky. 1969); Cudnik v. William Beaumont Hosp., 525 N.W.2d 891 (Mich. App. 1994); Ash v. N.Y. Univ. Dental Ctr., 564 N.Y.S.2d 308 (App. Div. 1990); Olson v. Molzen, 558 S.W.2d 429 (Tenn. 1977); *see also* A. M. Swarthout, Annotation, *Validity and Construction of Contract Exempting Hospital or Doctor from Liability for Negligence to Patient*, 6 A.L.R. 3d 704 (1966) (noting that rulings as to the validity of exculpatory contracts between hospitals or physicians and patients "indicate generally, but not uniformly, that contracts of the kind mentioned are invalid").

assumption of risk defenses, courts likewise generally reject these defenses on similar policy grounds.[124]

Critics correctly note that courts that reject contractual and tort-based defenses in medical malpractice cases "have not always provided a clear basis for their objections."[125] Mehlman, for example, argues that there has been "no consistency in the rationales offered by the courts, little practical guidance for future cases, and no way to distinguish cases that have invalidated such agreements as a matter of law from those that have upheld them or permitted their validity to be decided by a jury."[126] Others point out that even applying the clearly described *Tunkl* factors does not necessarily support the outcomes in many medical malpractice cases.[127] However, a careful analysis of case law demonstrates that the objections raised to defenses based on a patient's voluntary acceptance of risk fall into three general categories: those concerning the unwaivable nature of the duties owed by physicians, concerns about freedom of choice and disparities in bargaining power, and concerns about informational disparities.[128]

1. Unwaivable Duties

Many courts, in rejecting these defenses in malpractice cases against individual health care providers, conclude that the duty of health care professionals to provide non-negligent medical care is one that simply cannot be waived, whether by way of contract or by a patient's implicit

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124. *See, e.g.*, Morrison v. MacNamara, 407 A.2d 555, 567–68 (D.C. 1979) (holding that the trial court erred in allowing the jury to consider assumption of risk, noting that assumption of risk defenses have "rarely been sustained in actions involving professional negligence," for reasons including the knowledge disparity between doctor and patient, and the "greater duty" owed by physicians to patients); Storm v. NSL Rockland Place, LLC, 898 A.2d. 874, 886–87 (Del. Super. Ct. 2005) (applying *Tunkl* factors and finding that "primary assumption of risk" is not applicable in health care contexts because patients do not choose to be in need of medical care and because healthcare regulations prohibit patients from permitting providers to exercise less than ordinary care); Brady v. Urbas, 111 A.3d 1155 (Pa. 2015) (same).

125. Mehlman, *supra* note 75, at 357.

126. Mehlman, *supra* note 7, at 401.

127. *Id.* at 401–02; Mehlman, *supra* note 75, at 357 (noting that the *Tunkl* analysis "has been criticized as unpersuasive, incomplete, and inoperative"); Robinson, *supra* note 76, at 184.

128. The discussion below expands on Max Mehlman's excellent analysis in *Fiduciary Contracting*, in which he recognizes two of these categories—lack of choice and lack of information—and argues that they justify the outcomes in cases like *Schneider*, *Colton*, *Porubiansky*, and others. *See generally* Mehlman, *supra* note 7; *see also* Mehlman, *supra* note 75, at 357–59 (noting that the "latent explanation" courts offer for the outcomes in these cases is that contracts between physicians and patients are inefficient due to unequal bargaining power, incomplete information, and lack of meaningful alternatives).

agreement. As stated by the Delaware Superior Court in *Storm v. NSL Rockland Place, LLC*,[129] given the "strict legal, ethical, and professional standards that regulate the healthcare profession," there is "virtually no scenario in which a patient can consent to allow a healthcare provider to exercise less than 'ordinary care' in the provision of services."[130]

Some courts ground this duty in state laws of professional licensure, which grant health care providers licenses to practice on the condition that they satisfy the professional standards of care. In *Emory University v. Porubiansky*,[131] for example, the Georgia Supreme Court found that the physician's duty to exercise reasonable care is "an affirmative statutory duty imposed upon those who engage in professional practice."[132] Courts in Tennessee, New York, and Washington have offered similar justifications for rejecting defenses that would effectively eliminate the physician's duty to satisfy the standard of care.[133]

Other courts note that the duty to exercise due care is established in the common law of tort and reinforced by malpractice law, and therefore cannot be relieved by any contractual or consent-based agreement.[134] In

129. 898 A.2d 874 (Del. Super. Ct. 2005).

130. *Id.* at 874. In *Storm*, the court rejected what it termed the "primary assumption of risk" defense in a claim alleging substandard medical care. However, it held that the defendants could raise the defense of "secondary assumption of risk" in its efforts to prove that the plaintiff's conduct constituted contributory negligence. As explained in section II.A.3, however, the claim that a plaintiff has consented to substandard care is more accurately defined as secondary, not primary assumption of risk, so the court's choice of language is perplexing.

131. 282 S.E.2d 903 (Ga. 1981).

132. *Id.* at 905.

133. *See, e.g.*, Ash v. N.Y. Univ. Dental Ctr., 564 N.Y.S.2d 308, 310–11 (App. Div. 1990) (noting that the state "carefully regulates the licensing of physicians and other health care professionals and monitors such activities to prevent untoward consequences to the public from 'the ministrations of incompetent, incapable, ignorant persons'"); Olson v. Molzen, 558 S.W.2d 429, 432 (Tenn. 1977) ("We do not approve the procurement of a license to commit negligence in professional practice."); Kelly v. Carroll, 36 Wash. 2d 482, 502, 219 P.2d 79, 90 (1950) (holding that state licensing statutes, which are intended to protect patients from incompetent practitioners, are "incompatible with putting the individual to the hazard of risking incompetence in the selection of persons to treat him").

134. *See, e.g.*, *Storm*, 898 A.2d at 874 (noting that the assumption of risk defense is incompatible with state medical malpractice law and nursing home regulations); Spar v. Cha, 907 N.E.2d 974, 979 (Ind. 2009) ("The duty of a treating physician is ordinarily to deliver medical services that meet the standard of ordinary care."); *Ash*, 564 N.Y.S.2d at 311 (noting that "concern for the enforcement of established minimum standards of professional care provides the underlying rationale for a cause of action for malpractice in favor of those who have been subjected to substandard care"); Conrad-Hutsell v. Colturi, No. L-01-1227, 2002 WL 1290844, at *4 (Ohio Ct. App. May 24, 2002) (rejecting no-duty primary assumption of risk as a defense, holding that a patient's decision to exceed the physician's recommendation regarding narcotic dosage does not relieve the physician of a duty to monitor the patient for drug abuse, and finding that such an outcome would be "against public policy and render[] meaningless a physician's statutory obligations to his patients"); Brady v.

Schwartz v. Johnson,[135] for example, a Maryland appellate court denied a physician's attempt to raise assumption of risk as a defense, holding that allowing this defense "would mean that [the patient] consented to allow [the physician] to exercise less than ordinary care."[136] It concluded that a patient's consent to treatment cannot be used to "relieve the physician of compliance with the applicable standard of care."[137] Other courts have been even firmer in reaching this conclusion. The Fifth Circuit in *Kozan v. Comstock*,[138] applying Louisiana law in a medical malpractice case, concluded that "[t]he duty of due care is imposed by law and is something over and above any contractual duty. Certainly, a physician could not avoid liability for negligent conduct by having contracted not to be liable for negligence. The duty is owed in all cases, and a breach of this duty constitutes a tort."[139]

Finally, other courts frame the physician's unwaivable duty as effectively fiduciary in nature, grounded in professional ethics and the unique power relationship between physician and patient.[140] In *Ash v. New York University Dental Center*,[141] for example, a New York appellate court rejected a contractual waiver of liability in a malpractice case on public policy grounds. It noted that physicians owe "independent obligations" to patients based on their special relationship, one that "imposes upon the health care provider greater responsibilities than that required in the ordinary commercial market place."[142] Courts in many contexts have described the doctor-patient relationship as being

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Urbas, A.3d 1155, 1162 (Pa. 2015) ("There is no assumption-of-the-risk defense available to a defendant physician which would vitiate his duty to provide treatment according to the ordinary standard of care.").

135. 49 A.3d 359 (Md. Ct. Spec. App. 2012).

136. *Id.* at 373.

137. *Id.*

138. 270 F.2d 839 (5th Cir. 1959).

139. *Id.* at 845.

140. *See, e.g.*, Morrison v. MacNamara, 407 A.2d 555, 568 (D.C. 1979) (holding that "the nature of the doctor-patient relationship, which requires the patient to rely on the learning and judgment of the doctors, often precludes a finding that the doctor owed no duty to the patient," and that "the doctor generally owes a greater duty to his patient than the patient owes to himself"); Storm v. NSL Rockland Place, LLC, 898 A.2d 874, 884 (Del. Super. Ct. 2005) (holding that given the "strict legal, ethical, and professional standards that regulate the healthcare profession," there is "virtually no scenario in which a patient can consent to allow a healthcare provider to exercise less than 'ordinary care' in the provision of services"); Rosenthal v. Bologna, 620 N.Y.S.2d 376, 378 (App. Div. 1995) (rejecting liability waiver between patient and home health service provider, citing the "State's interest in the health and welfare of its citizens" and the "highly dependent (and thus unequal) relationship between patient and health care provider").

141. 564 N.Y.S.2d 308 (App. Div. 1990).

142. *Id.* at 311.

grounded in fiduciary principles, imposing additional duties on physicians for the protection of patients from abuse of power.[143]

While, in reaching these conclusions, some courts reference the experimental or alternative therapy cases described in section II.C as exceptions to this general rule, they offer no satisfactory explanations for why these exceptions are justifiable.[144]

2. Freedom of Choice and Disparities in Bargaining Power

Multiple factors cited in *Tunkl* to justify a public policy exception to enforcement of liability waivers speak to the patient's lack of bargaining power when seeking out medical treatment; many other courts have raised similar concerns. As the California Supreme Court wrote in *Tunkl*, patients seeking medical services are "in special need of the particular skill of [a hospital's] staff and facilities," and the provision of these services constitutes a "practical and crucial necessity" for patients.[145] Consequently, "[t]he would-be patient is in no position to reject the proffered agreement, to bargain with the hospital, or in lieu of agreement to find another hospital."[146] Courts considering assumption of risk defenses have raised similar concerns about the patient's lack of choice in the matter of whether to seek medical care, noting that unlike in other commercial transactions where assumption of risk may be used as a valid defense, a patient has little choice in pursuing treatment—she does so not "out of a desire to satisfy a personal preference,"[147] but out of medical necessity.

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143. *See* Hall, *supra* note 89, at 593 (citing case law holding that "physicians owe fiduciary-like duties to their patients"); Mehlman, *supra* note 7, at 388–90 (citing case law describing the physician-patient relationship as fiduciary in nature).

144. Spar v. Cha, 907 N.E.2d 974, 982 n.2 (Ind. 2009) (identifying, in a footnote, alternative therapy and Jehovah's Witness cases as "exceptional circumstance[s]" where assumption of risk can apply because "the patient's express refusal ahead of time relieves the physician of this duty"); Schwartz v. Johnson, 49 A.3d 359, 371 (Md. Ct. Spec. App. 2012) (citing cases of alternative therapy and patients' refusal to follow physician recommendations as ones where assumption of risk would be appropriate, but concluding that a patient will "almost never" voluntarily accept the risk that a physician will negligently perform a procedure).

145. Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 447 (Cal. 1963).

146. *Id.*; *see also* Rosenthal v. Bologna, 620 N.Y.S.2d 376, 378 (App. Div. 1995) (rejecting liability waiver between patient and home health service provider, citing the "highly dependent (and thus unequal) relationship between patient and health care provider"); Ash v. N.Y. Univ. Dental Ctr., 564 N.Y.S.2d 308, 311 (App. Div. 1990) (in rejecting a liability waiver, noting that the inequality of bargaining power between patient and health care provider, where one party "must either accept what is offered or be deprived of the advantages of the relation," creates a "substantial opportunity for abuse").

147. Storm v. NSL Rockland Place, LLC, 898 A.2d 874, 883–84 (Del. Super. Ct. 2005); *cf. id.* at 886 (noting that the question of whether a patient had sufficient bargaining power when signing a

Some courts, in pointing to the patient's lack of bargaining power, also reference the potentially discriminatory and disparate impact that acceptance of such defenses might have on patients with limited resources. If physicians were permitted to rely on these defenses under ordinary circumstances, surely patients of financial means would attempt to negotiate to retain their right to sue for malpractice. Patients who lack the financial resources to negotiate with their providers, however, would find themselves without a remedy. As the court in *Tunkl* wrote, "[t]o immunize the hospital from negligence as to the charitable patient because he does not pay would be as abhorrent to medical ethics as it is to legal principle."[148] A later New York case, also dealing with a health care institution that served low-income clients, raised similar concerns.[149] The New York court noted that patients who receive services at low-income dental clinics out of financial necessity "cannot be considered to have freely bargained for a sub-standard level of care in exchange for a financial savings."[150] Upholding exculpatory clauses, the court held, would lead to an "invidious result"—"a *de facto* system in which the medical services received by the less affluent are permitted to be governed by lesser minimal standards of care and skill than that received by other segments of society."[151]

3. Information Disparity

Finally, many courts rejecting assumption of risk defenses in malpractice cases do so on the basis that assumption of risk requires a patient's knowing appreciation of risk, and that the information disparity between doctor and patient necessarily makes this impossible.[152] As

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contractual exculpatory agreement is "not applicable in assessing whether a primary assumption of the risk defense violates public policy").

148. *Tunkl*, 383 P.2d at 448.

149. *Ash*, 564 N.Y.S.2d at 308.

150. *Id.* at 371–72.

151. *Id.* at 370.

152. *See, e.g.*, *Storm*, 898 A.2d at 884 (holding that the information disparity between doctor and patient precludes the use of assumption of risk as a defense, citing courts in other jurisdictions using similar reasoning); Spar v. Cha, 907 N.E.2d 974 (Ind. 2009) (citing *Storm* and *Morrison* to this effect); Schwartz v. Johnson, 49 A.3d 359, 372 (Md. Ct. Spec. App. 2012) (holding that "the very nature of actions involving medical malpractice," in which there is a significant disparity in knowledge between doctor and patient, precludes the use of assumption of risk as a defense); *see also* Hardi v. Mezzanotte, 818 A.2d 974, 980 (D.C. 2003) (in ruling on a statute of limitations issue, holding that due to the information disparity between doctor and patient, "patient can not be expected to know that the doctor's actions might be negligent and result in harm or to question them").

noted in *Morrison v. MacNamara*,[153] a case reversing a trial court's decision to allow the jury to consider assumption of risk as a defense to medical malpractice, "the disparity in knowledge between professionals and their clientele generally precludes recipients of professional services from knowing whether a professional's conduct is in fact negligent."[154]

In cases dealing with contractual defenses, in contrast, there is no requirement that a patient knowingly enter into a relationship that will involve negligent conduct. However, because understanding of the bargain struck is a necessary component of any enforceable exculpatory clause, some contractual waivers in the health care context have been struck down due to lack of clarity as to the terms of the agreement.[155] Such cases likewise reflect courts' concerns about patients' lack of information as compared to their health care providers, albeit here, legal information rather than medical information.

C. Cases Limiting Physician Liability

Despite the vigor with which many courts reject the notion that a patient may be deemed to have consented to negligent medical care, there are a few contexts in which courts have been willing to accept defenses based on a patient's voluntary acceptance of risk. For the purposes of this Article, the two most relevant contexts involve experimental or alternative therapies, and surgical treatment constrained by Jehovah's Witnesses' beliefs regarding the use of blood products.[156]

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153. 407 A.2d 555, 567 (D.C. 1979).

154. *Id.*; *see also* Hall & Schneider, *supra* note 7, at 761 ("If courts rigorously apply informed-consent law to assumption of risk, '[o]nly in rare circumstances would a patient be considered to have assumed the risk of negligent medical treatment' because 'most patients' knowledge of medicine does not permit them to understand these risks." (alteration in original) (quoting Murphy, *infra* note 156, at 162)).

155. *See, e.g.*, Abramowitz v. N.Y. Univ. Dental Ctr., Coll. of Dentistry, 494 N.Y.S.2d 721, 724 (App. Div. 1985) (rejecting an exculpatory clause on the grounds that the contractual language did not "unmistakenly express an intention on the part of the plaintiff to absolve the defendant of liability for its own negligence"); Leidy v. Deseret Enters., Inc., 381 A.2d 164, 169 (Pa. 1977) (noting that plaintiff who suffered injury at a health spa should be able to present evidence as to whether she was "aware" that the exculpatory clause she signed would release the spa and its employees (including physicians and physical therapists) from liability); Poag v. Atkins, 806 N.Y.S.2d 448, 2005 WL 2219689, at *3 (Sup. Ct. Sept. 12, 2005) (unpublished table decision) (rejecting exculpatory agreement in a medical malpractice case because "no separate heading or caption was present to alert the decedent that she was foregoing the right to bring suit").

156. Similar defenses have also been raised by physician-defendants where a patient fails to follow medical advice, refuses recommended treatment, or makes misrepresentations that affect her medical care. *See* Sharon W. Murphy, *Contributory Negligence in Medical Malpractice: Are the Standards Changing to Reflect Society's Growing Health Care Consumerism?*, 17 U. DAYTON L. REV. 151, 167–72 (1991). These cases—in which a patient's unreasonable conduct or lack of due

In the alternative therapy cases, patients argue that their health care providers deviated from the standard of care in offering the treatment in question—that is, even if the treatment was performed as intended, it fell outside the standard of care. Physicians in these cases defend themselves on the grounds that their patients freely and knowingly consented to an inherently risky treatment. In the Jehovah's Witness cases, in contrast, patients typically allege that some unanticipated negligence occurred during the performance of surgery. The patients in these cases have previously consented to receiving surgical treatment without the use of blood or blood products, and their physicians claim that this consent relieves them of liability for injuries resulting from blood loss, even if that blood loss was occasioned by the physician's unanticipated negligence.[157]

In both contexts, courts have been receptive to physicians' defensive arguments grounded in the patient's implied or express acceptance of risk. However, the reasoning offered by courts in these cases is often quite underdeveloped. While some offer justifications for why physicians should not be liable for deviating from the standard of care in these contexts, many courts fail to acknowledge the patient-protective arguments described above in section II.B, and therefore fail to explain why these contexts justify a deviation from those traditional principles.

1. Experimental or Alternative Therapies

The first line of medical malpractice cases in which courts are willing to enforce waivers of liability and recognize assumption of risk as a defense involves experimental or alternative treatments. In such cases, a patient is offered the opportunity to receive a risky experimental or alternative therapy and chooses to proceed with full knowledge of the treatment's risks, benefits, and alternatives.[158] When the patient later sues the physician for malpractice, the physician may be permitted to defend herself on the grounds of the patient's contractual waiver of

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care contributed to her injury—are most often analyzed under the doctrine of comparative negligence, rather than assumption of risk. *Id.* There appears to be little, if any, concern that reduction of damages in these contexts is inappropriate. Moreover, they are distinguishable from the alternative therapy and Jehovah's Witness contexts because they do not involve patients who voluntarily and knowingly agree to pursue potentially negligent treatment freely offered by physicians—rather, the patient's unreasonable conduct in the comparative negligence cases is at odds with the physicians' expectations or recommendations regarding treatment.

157. *See infra* section II.C.2.

158. *But see infra* note 163.

liability or implied assumption of risk.[159] Typically, in these cases, there is no allegation that the physician *performed* a treatment negligently. Rather, the allegation is that the physician's *selection and recommendation* of the treatment was negligent—in other words, that the treatment itself was so far outside the standard of care that it would constitute malpractice even if performed as intended.[160]

For example, a series of New York cases involved patients suffering from cancer who sought treatment from physicians offering alternatives to radiation and chemotherapy.[161] Some of the physicians informed their patients that the treatments were experimental, or not guaranteed to be effective.[162] However, others did not disclose the experimental nature of the treatments, or claimed unreasonable success rates.[163] Nevertheless, in all four cases, courts allowed the defendant physicians to argue that their patients' recovery should be reduced or barred entirely because they voluntarily assumed the risk of treatment with full knowledge of its risks and benefits.[164] In two of these cases, where the patients had signed

159. *See generally* LUCINDA JESSON & STACEY TOVINO, COMPLEMENTARY AND ALTERNATIVE MEDICINE AND THE LAW 152–56 (2010) (discussing the assumption of risk defense in the context of alternative medicine).

160. *See, e.g.*, Charell v. Gonzalez, 660 N.Y.S.2d 665, 665 (Sup. Ct. 1997) (noting that a treatment described as "'non-conventional' may well necessitate a finding that the doctor who practices such medicine deviates from 'accepted' medical standards"); Colton v. N.Y. Hosp., 414 N.Y.S.2d 866, 876 (Sup. Ct. 1979) (describing the experimental treatment in question as one that "because of its inherent dangers, may ordinarily be in and of itself a departure from customary and accepted practice (and thus possibly actionable as malpractice) even if performed in a non-negligent manner").

161. Boyle v. Revici, 961 F.2d 1060 (2d Cir. 1992); Schneider v. Revici, 817 F.2d 987 (2d Cir. 1987); Charell v. Gonzalez, 673 N.Y.S.2d 685 (App. Div. 1998); Poag v. Atkins, 806 N.Y.S.2d 448, 2005 WL 2219689 (Sup. Ct. Sept. 12, 2005) (unpublished table decision).

162. *Boyle*, 961 F.2d at 1062 (the patient was informed that the medications used were not FDA approved, and that the physician "could offer no guarantees"); *Schneider*, 817 F.2d at 989 (the consent form stated the patient's understanding that "some of the treatment procedures and medications are still investigatory awaiting further research and submission for F.D.A. approval").

163. In *Charell*, the patient also brought suit for lack of informed consent, claiming the physician told her that his treatment had a 75% success rate and failed to provide her with information about the risks of treatment. Nevertheless, the court found that while there was evidence to support a finding of lack of informed consent, there was also evidence to support a finding that the patient had sufficient knowledge of the risks of treatment from sources other than her physician, and so could be found to have impliedly assumed the risk of treatment. *Charell*, 660 N.Y.S.2d at 665. In *Poag*, the physician allegedly told the patient that the alternative treatment could "definitely cure" her breast cancer; the court nevertheless concluded that there was a triable issue of fact as to what risks the plaintiff was actually informed of and whether she impliedly assumed these risks. *Poag*, 806 N.Y.S.2d, 2005 WL 2219689, at *1, *3.

164. *Boyle*, 961 F.2d at 1061–62 (reversing trial court's rejection of jury instructions on express assumption of risk, despite the absence of a signed consent form); *Schneider*, 817 F.2d at 996 (reversing trial court's rejection of jury instructions on express assumption of risk, finding that there

consent forms purporting to release their physicians from liability, the courts held that the contractual waivers were unenforceable, but nevertheless allowed the juries to consider express assumption of risk as a defense.[165]

Surprisingly, some of the opinions upholding assumption of risk and contractual waivers as defenses in alternative therapy cases do not acknowledge that courts have traditionally rejected these defenses in medical malpractice contexts.[166] And as compared to the many cases in which assumption of risk and waiver defenses have been rejected after extensive analysis of policy arguments, the reasoning in these opinions seems quite underdeveloped. Courts that support express or implied assumption of risk defenses in experimental or alternative therapy cases justify their holdings quite simply by pointing to the societal value of allowing informed patients to pursue innovative treatments that fall outside the standard of care. However, these courts offer no clear guidance as to where one might draw the line between permissible and impermissible deviations from the standard of care.

Colton v. New York Hospital[167] is one example of a case where the court justified its holding by reference to the societal value of the treatment in question. In *Colton*, two patients were injured as a result of an experimental kidney transplant procedure that the court described as being so inherently dangerous that it might "ordinarily be in and of itself a departure from customary and accepted practice (and thus possibly

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was sufficient evidence to present the issue to the jury; but upholding court's refusal to submit consent form to the jury on the grounds that the form was not an unequivocal release of liability); *Charell*, 673 N.Y.S.2d at 686–87 (refusing to vacate jury finding that patient impliedly assumed the risk of treatment); *Poag*, 806 N.Y.S.2d, 2005 WL 2219689, at *3 (denying motions for summary judgment so that express assumption of risk defense, based on patient's signature on informed consent form, could be presented at trial; but finding that the exculpatory agreement in the consent form signed by the patient was unenforceable as violating public policy).

165. In *Schneider*, this outcome was understandable—the court found that the consent form signed by the patient did not unequivocally release the doctor from liability and so was not enforceable as a matter of contract, but that it could be used as evidence to support the assertion that the patient voluntarily, knowingly, and explicitly assumed the risk of treatment. *Schneider*, 817 F.2d at 993, 996. In *Poag*, however, the court's conclusion is somewhat perplexing—it denied the physician's contractual defense on the grounds that releases from medical malpractice are against public policy, but nevertheless permitted the defendants to make the same argument as a matter of tort law via the doctrine of express assumption of risk. *Poag*, 806 N.Y.S.2d, 2005 WL 2219689, at *3. It is unclear why, if barring a patient's right to sue for medical malpractice violates public policy when the patient signs a document to that effect, those same policy reasons would not cause the court to reject express assumption of risk (also a total bar on recovery) as a defense.

166. *But see Poag*, 806 N.Y.S.2d, 2005 WL 2219689, at *3 (refusing to enforce exculpatory clause in a consent document on the grounds that policy reasons "typically" bar enforcement of such contractual agreements, but allowing express assumption of risk to be presented as a defense).

167. 414 N.Y.S.2d 866 (Sup. Ct. 1979).

actionable as malpractice) even if performed in a nonnegligent manner."[168] Nevertheless, the court held that when a patient voluntarily undergoes a risky procedure, the parties may covenant to release the physician from liability for proper performance of that procedure.[169] It justified its conclusion by pointing to "public policy encouraging such necessary activity as experimental medical research,"[170] and noted that this policy goal could not be achieved if patients were permitted to sue. It did not, however, address whether other policy goals might likewise be achieved by enforcing covenants not to sue in other medical contexts. And perhaps most strikingly, although the court cited *Tunkl* in its discussion of legal terminology,[171] nowhere did it acknowledge the primary holding of the *Tunkl* decision or the implications of that decision—namely, that releases of liability for negligence by health care institutions and providers generally violate public policy.

The court in *Schneider v. Revici*[172] relied on similar reasoning when it allowed a jury to consider express assumption of risk in a case where a patient with breast cancer sought out non-invasive therapy that had not been adopted by the medical community.[173] As in *Colton*, the allegations of malpractice in *Schneider* related to the provision of the alternative treatment itself—not any negligence in the administration or performance of that treatment. The court held that an informed decision to reject conventional cancer therapy and seek out alternative treatments is within the patient's right "to determine what shall be done with his own body," but offered no guidance as to whether there are any contexts in which this right of self-determination might justifiably be limited.[174] Unlike the court in *Colton*, it acknowledged the plaintiff's argument that public policy generally opposes the use of assumption of risk to "dissolve the physician's duty to treat a patient according to medical community standards," but quickly dismissed that argument by pointing

168. *Id.* at 876.

169. *Id.*

170. *Id.* at 875 (The court specifically referenced New York legislation favoring kidney transplant programs, and federal and state subsidies of kidney transplants and experimental medical research programs. Note, however, that the kidney transplant at issue in this case was being provided for the purposes of clinical treatment, and not for research purposes).

171. *Id*. at 964 (citing *Tunkl* in its discussion of the distinctions between waivers, releases, covenants not to sue, and exculpatory clauses).

172. 817 F.2d 987 (2d Cir. 1987).

173. *Id.* at 995.

174. *Id.*

out that no such public policy had been statutorily enacted.[175] The court ultimately concluded that there is no policy reason to prevent a patient from "go[ing] outside currently approved medical methods" in pursuit of treatment.[176]

In *Charell v. Gonzalez*,[177] the court recognized the defendant's argument that the practice of alternative medicine would be chilled if the verdict against the physician were upheld.[178] Unlike the court in *Schneider*, the *Charell* court did not explicitly opine on the value of alternative and experimental treatments such as the ones offered by the defendants. However, it seemed to acknowledge that refusing to recognize assumption of risk and waiver defenses would chill these practices, noting that the only way physicians could offer such a "non-conventional" therapy is if their patient "execute[d] a comprehensive consent containing appropriate information as to the risks involved" that could then be relied upon as proof of the patient's voluntary acceptance of specific risks.[179] Like the court in *Colton*, it did not mention the traditional public policy objections to the enforcement of contractual waivers or the use of assumption of risk defenses in medical malpractice cases, and offered no indication of whether these defenses could be used beyond the context of alternative or experimental cancer treatment.

In sum, the courts that have accepted claims that patients' recovery for malpractice should be barred or limited if they knowingly chose to pursue risky experimental or alternative therapy have justified their decisions for reasons of public policy. They conclude that because there is value in medical experimentation, and because patients have the right to make medical decisions about their bodies, a patient's agreement to pursue unconventional treatment can and should be viewed either as a decision to release the physician from the duty to provide standard medical care (barring recovery entirely) or as a justifiable reason to reduce recovery. These courts do not, however, explain why these policy arguments override the argument that the duties of care imposed on physicians by statute, common law, and professional ethics are

175. *Id.* (noting that under New York common law, waivers of liability do not violate public policy unless there are statutory limitations on such agreements (citing Arbegast v. Bd. of Educ., 65 N.Y.2d 161, 170 (1985))).

176. *Schneider*, 817 F.2d at 995; *see also* Boyle v. Revici, 961 F.2d 1060 (2d Cir. 1992) (relying on the reasoning in *Schneider*).

177. 660 N.Y.S.2d 665 (Sup. Ct. 1997).

178. *Id.* at 668.

179. *Id.* Interestingly, *Charell* was one of the cases in which the physician failed to inform the patient of the risks of treatment. *See supra* note 163.

fundamentally unwaivable.[180] Moreover, these cases do not resolve the question of whether there are other contexts, beyond experimental or alternative therapy, in which public policy might support patients' autonomous decisions to pursue treatment that falls outside the standard of care.

2. Jehovah's Witness Refusal of Blood

The second category of malpractice cases in which courts regularly permit the use of voluntary acceptance of risk defenses involves Jehovah's Witness patients whose religious beliefs prohibit the use of blood or blood products. Typically, these cases arise when a physician's negligent performance of a surgical operation results in an injury that is exacerbated by the patient's refusal to accept transfused blood. Most courts in these cases hold that while patients who refuse blood for religious reasons do not assume the risk of the physician's negligence, they *do* assume the risk of harm resulting from refusal to accept blood.[181]

The strongest policy justification that has been offered in support of this conclusion is that, in the absence of such liability protections, physicians would be unwilling to accept and treat Jehovah's Witness patients.[182] In *Shorter v. Drury*,[183] the court described such an outcome as "repugnant in a society which attempts to make medical care available to all its members."[184] That said, many courts adjudicating Jehovah's Witness cases permit defendants to present contractual or tort-based defenses based on the patient's voluntary acceptance of risk without considering policy justifications at all. Rather, they simply analyze these defenses as they would in any other tort action—by looking to whether the language in a signed release was specific enough,[185] or referencing state constitutional provisions requiring jury

180. *See supra* section II.B.1.

181. *See* cases cited *infra*, note 194. *But see* Garcia v. Edgewater Hosp., 613 N.E.2d 1243, 1251 (Ill. App. Ct. 1993) (holding that signed release barred patient's claim against the hospital for injuries resulting from implantation of a defective heart valve).

182. Shorter v. Drury, 103 Wash. 2d 645, 652–53, 695 P.2d 116, 120–21 (1985).

183. 103 Wash. 2d 645, 695 P.2d 116 (1985).

184. *Id.* at 652, 695 P.2d at 121.

185. *See, e.g.*, *Garcia*, 613 N.E.2d at 1251 (holding that release signed by Jehovah's Witness patient barred suit as a matter of law, finding that there were no policy reasons to bar enforcement of the release, which "explicitly delineated the desires and intentions of both parties"); Corlett v. Caserta, 562 N.E.2d 257 (Ill. App. Ct. 1990) (holding that release signed by Jehovah's Witness patient did not bar malpractice suit, because the language of the release did not specifically relieve physician from liability for negligence in diagnosis and treatment).

determinations of assumption of risk.[186] As with many of the experimental and alternative treatment cases, courts in blood refusal cases rarely acknowledge the traditional bar on assumption of risk and contractual waiver in medical malpractice cases, and offer little to no justification for their deviation from these traditional principles.[187] In *Garcia v. Edgewater Hospital*,[188] for example, the court recognized that "exculpatory contracts are not favored" and will not be enforced if they are "against public policy," but ultimately concluded, without further analysis, that "there are no policy reasons which would indicate that the releases [signed by the Jehovah's Witness plaintiff] should not be upheld."[189]

However, there are two peculiarities in these cases that distinguish them from the experimental and alternative therapy cases described above. First, unlike the experimental treatment cases, the plaintiffs in blood refusal cases are not explicitly alleging that surgery without the use of blood—that is, the *offering* of this type of treatment—in and of itself constitutes negligence. Rather, the alleged negligence involves unanticipated errors in the *performance* of the surgery. That said, there is no logical way to interpret these cases without conceding that the offering of bloodless surgery could constitute malpractice even in the absence of any errors in performance. Jehovah's Witness patients are regularly asked to sign legal waivers in connection with their refusal of blood products, and at least one court has explicitly acknowledged that assumption of risk and waiver defenses are necessary to ensure that physicians who treat these patients are protected from liability.[190] The necessary but unspoken underlying assumption, of course, is that physicians who perform surgery on Jehovah's Witness patients in accordance with their religious limitations are at risk of being found negligent even if they perform the surgery with all due care—otherwise

186. Estate of Reinen v. N. Ariz. Orthopedics, Ltd., 9 P.3d 314 (Ariz. 2000) (finding that jury instructions defining the specific risks the plaintiffs did and did not assume violated Arizona constitutional requirement that defenses of contributory negligence and assumption of risk be left to the jury).

187. Of the Jehovah's Witness cases cited herein, only *Shorter v. Drury* explicitly references *Tunkl* and similar cases barring enforcement of releases in medical malpractice cases. *Shorter*, 103 Wash. 2d at 652–53, 695 P.2d at 120–21.

188. 613 N.E.2d 1243 (Ill. App. Ct. 1993).

189. *Id.* at 1251.

190. *Shorter*, 103 Wash. 2d at 652–53, 695 P.2d at 120–21. That said, the court in *Shorter* seemed to be addressing the risk of liability if the physician were to administer blood against the patient's wishes, and not liability for deviating from the standard of care.

there would be no need for such waivers.[191] Surely, if an expert testified that performing a given surgical procedure without blood or blood products would, under ordinary circumstances, be negligent, a plaintiff's attorney might successfully argue that the act constitutes malpractice regardless of the identity of the patient.[192] While the development of "bloodless surgery" and its increased use by non-religious patients may make this argument more challenging to present,[193] it seems to be an unstated presumption in Jehovah's Witness cases that surgery without blood exposes physicians to liability risk for operating outside the standard of care.

A second peculiar element of these cases is courts' insistence that Jehovah's Witness patients who sign releases of liability are only assuming the risks of harm associated with refusing blood and are not assuming the risks of physician negligence.[194] Courts rely on this reasoning to permit malpractice suits against physicians to proceed, but then—curiously—nevertheless allow damages to be reduced. If the patient has not assumed the risk of physician negligence, then why is it justifiable to reduce her damages on assumption of risk grounds?

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191. In this way, Jehovah's Witness cases can be distinguished from more traditional cases of treatment refusal. Modern principles of law and medical ethics bar physicians (in all but the most exceptional circumstances) from providing treatment to an informed and competent patient who refuses treatment. In such cases, withholding unwanted treatment does not constitute malpractice; rather, it protects physicians from allegations of battery. However, there is a difference between merely withholding unwanted treatment while providing all other care in according with medical standards (for example, withholding unwanted dialysis from a dying patient but providing competent palliative care), and withholding unwanted treatment while instead actively providing risky treatment that falls outside the standard of care.

192. The success of this argument would depend on the jury's interpretation of medical custom and of the expectations of a reasonable physician acting "in like circumstances." *See supra* section I.B.

193. *See* Amanda Schaffer, *Should Anyone Be Given a Blood Transfusion?*, NEW YORKER (Aug. 13, 2015), https://www.newyorker.com/news/news-desk/should-anyone-be-given-a-blood-transfusion [https://perma.cc/28JQ-PX4C] (describing the development of bloodless surgery and research supporting its efficacy and safety).

194. Estate of Reinen v. N. Ariz. Orthopedics, Ltd., 9 P.3d 314, 319 (Ariz. 2000) (rejecting trial court's assumption of risk jury instruction on the grounds that jury was required to make these factual determinations, where jury instruction established that plaintiff "did not voluntarily assume the risk of negligence by the Defendants, but . . . did voluntarily assume the risks relating to the refusal to take or receive transfusions of blood or blood products"); Corlett v. Caserta, 562 N.E.2d 257, 261 (Ill. App. Ct. 1990) (holding that the release barred liability for negligence in respecting patient's refusal of a blood transfusion, but did not bar liability for negligence in diagnosis and treatment of a medical condition, though plaintiff's recovery could be reduced for failure to mitigate damages); *Shorter*, 103 Wash. 2d at 652–53, 695 P.2d at 124 ("Mr. and Mrs. Shorter did not assume the risk of the negligence. The risk they did assume was the risk of death as the consequence of their refusal to permit a blood transfusion.").

Presumably, when courts distinguish between assuming the risk of negligence and assuming the risk of blood loss, what they really mean is that the patient has not relieved the physician of the duty to exercise due care in the performance of a medical procedure but *has* relieved the physician of the duty to administer blood in the event of medical necessity. In other words, a patient's suit would be barred if it were predicated *solely* on the physician's decision not to provide a blood transfusion, but the patient would still be permitted to sue if she alleged other negligent conduct on the part of the physician. In *Garcia*, for example, the court distinguished between cases alleging negligent diagnosis and treatment (which it stated would not be barred by a Jehovah's Witness release), and cases "predicated upon the defendant doctor's respect for the decedent's refusal to transfuse blood."[195] And this distinction surely makes sense. A release of liability that relieves a physician of the duty to administer blood should not bar suit if the physician commits some other type of malpractice. But why, then, should assumption of risk doctrine reduce the Jehovah's Witness patient's damages at all?

In *Shorter*, for example, the court held that the patient did not assume the risk of the "direct consequences" of the physician's negligence, but did assume the risk of death as a consequence of refusing blood "under any circumstances *including where the doctor made what would otherwise have been correctable surgical mistake*."[196] As noted by the dissent, however, there is a substantial difference between assuming the risk of refusing blood in a procedure that is performed with due care, and assuming the risk of refusing blood "even when the blood was required because the doctor was negligent."[197] Treating the two as equivalent "in effect hold[s] that the [patient] assumed the risk of the doctor's

195. Garcia v. Edgewater Hosp., 613 N.E.2d 1243, 1251 (Ill. App. Ct. 1993). In light of the distinction drawn by the court, however, the outcome in *Garcia* is particularly perplexing. Garcia sued the hospital for breach of implied warranty of merchantability, alleging that the hospital's use of a defective heart valve caused the patient's heart surgery to take longer than expected, which in turn led to a clotting disorder and blood loss that caused the patient's death. *Id.* at 1246–47. The court concluded that a release signed by the patient completely barred suit against the hospital. *Id.* at 1250–51. The release noted that "unforeseen conditions" might arise during the procedure that would necessitate the use of blood, denied authorization for blood transfusion, and released the hospital and its physicians from liability "[i]n the event of my death as a result of not administering blood." *Id.* However, the patient's suit was explicitly predicated on the hospital's breach of duty in providing a defective heart valve, and *not* its "respect for the decedent's refusal to transfuse blood." *Id.* at 1251. Accordingly, under the distinction drawn by the court in *Garcia*, the patient's suit should not have been barred.

196. *Shorter*, 103 Wash. 2d at 656, 695 P.2d at 123 (emphasis added).

197. *Id.* at 660, 695 P.2d at 125 (Pearson, J., dissenting).

negligence."[198] The more reasonable interpretation of the patient's refusal (and one that the plaintiffs in *Shorter* conceded was their understanding at the time they signed the refusal form) is that it "represents [only] their assent to relieve [the physician] of his duty to administer blood if required by the non-negligent performance of the procedure."[199] If a court's finding that a Jehovah's Witness patient who refuses blood has not assumed the risk of the physician's negligence is to have any merit, then express or implied assumption of risk doctrine should not be used to reduce damages when the patient suffers injury resulting from such negligence.[200] Of course, there may be other doctrines that would allow for a reduction in the patient's recovery—for example, mitigation of damages.[201]

In sum, the reasoning used by courts in Jehovah's Witness blood refusal cases to justify enforcement of contractual releases or application of assumption of risk doctrine is puzzling. While their decisions are ostensibly justified on policy grounds—in an effort to ensure that Jehovah's Witness patients are neither rejected by physicians nor forced into treatment that violates their religious beliefs[202]—most courts fail to explain why these policy justifications override the policy arguments noted in *Tunkl* and other cases.[203] Moreover, courts' insistence that Jehovah's Witness patients are not assuming the risk of physician negligence seems inconsistent with their application of assumption of risk principles to reduce recovery when physicians are charged with medical malpractice.

III. JUSTIFYING THE "EXCEPTIONAL" CASES

As described in section II.B, there are three primary lines of objection to the use of contract- or tort-based defenses grounded in a patient's voluntary acceptance of risk: objections based on the strength of the

198. *Id.*

199. *Id.*

200. *Id.* ("The majority concedes the Shorters did not expressly assume the risk of the doctor's negligence. Having decided that, it logically follows that the Shorters did not expressly assume the risk of bleeding to death as a result of refusing blood, where the need for such blood resulted from the doctor's negligence rather than from the risks inherent in the procedure itself.").

201. *See* Corlett v. Caserta, 562 N.E.2d 257, 261–62 (Ill. App. Ct. 1990) (holding that the patient's religious refusal to accept blood does not exempt him from the duty to mitigate damages).

202. *See* Hall & Schneider, *supra* note 7, at 775 (in the context of patients requesting substandard treatment, noting that in the absence of contractual protections, a physician's "only alternatives are to fire the patient or insist that the patient accept unwanted treatment").

203. *See supra* section II.B.

physician's tort, fiduciary, and professional duties; objections based on the patient's lack of choice and bargaining power; and objections based on the information disparity between doctor and patient. And yet, these concerns appear to have been swept aside by courts in the limited contexts of experimental and alternative therapy and Jehovah's Witness patients, often with little explicit justification. These cases make clear that the traditionalist arguments grounded in patient vulnerability and physician duty cannot be relied upon to support an absolute prohibition on the use of such defenses.

This Part revisits the arguments that courts have used to justify the law's patient-protective attitude with respect to contract and tort defenses to medical malpractice. It closely examines the Jehovah's Witness and alternative therapy cases and concludes that the courts deciding these cases—though rarely addressing these arguments directly—had good reasons to conclude that the traditional bar on such defenses was not appropriate in these contexts.[204] But in failing to make clear exactly why these cases warrant an exception from the traditional rule, the courts also failed to recognize that the justifications for treating these cases differently could be extended to many other contexts in which patients seek out treatment that potentially falls outside the standard of care. Thus, this Part concludes that, in an era of consumer-directed care, perhaps these "exceptional" cases are not as exceptional as they first might seem.

A. Unwaivable Duties

The first argument that courts and commentators frequently raise when rejecting defenses grounded in a patient's voluntary acceptance of risk is that a physician's duty to deliver medical treatment in accordance with the standard of care is absolute and cannot be waived by the patient's voluntary agreement. According to this view, physicians' duties are established not only by state licensing and medical malpractice laws, but also by fiduciary and ethical principles crafted to protect patients who hold a position of disadvantage in an inherently unequal power relationship. Thus, patients should have no more ability to relieve their physicians of duty to provide non-negligent care than the beneficiary of a trust could relieve a trustee of the duties of loyalty and care.

While this claim is fundamentally appealing, it is impossible to reconcile with the fact that numerous courts have effectively negated the

204. *See also* Mehlman, *supra* note 7 (concluding that the outcomes in these outlier cases are justified because the cases satisfied the conditions for effective contracting).

physician's duty to provide non-negligent care by allowing assumption of risk and waiver defenses to be presented in experimental and alternative treatment and Jehovah's Witness cases. While there is sure to be some disagreement about whether a given treatment falls outside the standard of care, there can be no question that some of the cases where these defenses were permitted involved treatments that posed such serious risks that the medical community as a whole rejected them as valid medical approaches. In *Charell v. Gonzalez*, for example, a physician practicing alternative medicine suggested that a patient with uterine cancer be treated with a special diet and six coffee enemas a day, which he assured her had a 75% success rate.[205] In *Boyle v. Revici*,[206] all the parties stipulated that Dr. Revici's methods for treating cancer—which apparently consisted of urinalysis and ingestion of "various mineral compounds,"[207]—vinegar, baking soda, and eggs[208]—constituted violations of the standard of care.[209] In *Poag v. Atkins*,[210] the physician of a patient with breast cancer encouraged her to forgo radiation and chemotherapy, and instead recommended a regimen of vitamins and antioxidants that medical groups considered unsafe but that the defendant physician alleged would "definitely cure" the patient's cancer.[211] Courts' willingness to accept assumption of risk and waiver of liability defenses in these cases seems entirely inconsistent with the principle that physicians cannot be relieved of the duty to provide treatment that satisfies professional standards of care.

As noted in section II.C, the best justifications offered by courts that have permitted these defenses to proceed are grounded in policy preferences. In the alternative treatment and religious refusal contexts, courts have concluded—either explicitly or implicitly—that society would be better off allowing such treatments to continue, even though they may fall outside the professional standard of care. For example, in *Colton*, the court allowed defendants to rely on a covenant not to sue in a

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205. Charell v. Gonzalez, 673 N.Y.S.2d 685, 666 (App. Div. 1998). In *Charell*, the lower court's jury unanimously concluded that the physician's treatment constituted malpractice and awarded the plaintiff over $4.5 million in damages. *Id.* at 667. The jury's conclusions were upheld on appeal, as was its compensatory damage award (a $150,000 punitive damages award was later vacated). *Id.* at 686.

206. 961 F.2d 1060 (2d Cir. 1992).

207. *Id.* at 1062.

208. *See* Revici v. Comm'r of Educ., 546 N.Y.S.2d 240, 242 (1989).

209. *Boyle*, 961 F.2d at 1062.

210. 806 N.Y.S.2d 448, 2005 WL 2219689 (Sup. Ct. Sept. 12, 2005) (unpublished table decision).

211. *Id.* at *1.

malpractice case concerning a highly experimental kidney transplant procedure on the grounds that federal and state legislation indicated a "public policy encouraging such necessary activity as experimental medical research."[212] In *Shorter*, the court justified its acceptance of an express assumption of risk defense by reference to policy considerations, noting that the alternative to allowing such defenses in Jehovah's Witness cases would be a refusal by doctors to accept patients with certain religious beliefs, an outcome that the court described as "repugnant in a society which attempts to make medical care available to all its members."[213] In other words, if society would benefit from the provision of unorthodox and potentially negligent treatment, physicians ought to be allowed to provide it to informed patients without fear of liability.

If courts in some cases are willing to accept these consequentialist arguments, then clearly the duty-based principle requiring physicians to provide treatment in accordance with the standard of care is not absolute. Indeed, many commentators have taken this argument and applied it to a broader variety of contexts beyond those of religious refusal and experimental or alternative therapy. Scholars have argued that if we as a society truly want to promote innovation,[214] or cost-effective care,[215] or some other form of creativity in the delivery of medical treatment, then assumption of risk and contractual waiver must be accepted as valid defenses. The alternative, they claim, is that physicians with no protection against litigation will either be unwilling to accept patients seeking such treatment or will resort to coercing patients to accept the standard of care.[216]

But the challenges to implementing policy-based exceptions to physicians' duties of care—and drawing clear lines between cases where defenses will be recognized and where they will be rejected—should be

212. Colton v. N.Y. Hosp., 414 N.Y.S.2d 866, 875 (Sup. Ct. 1979).

213. Shorter v. Drury, 103 Wash. 2d 645, 652–53, 695 P.2d 116, 120–21 (1985).

214. *See, e.g.*, Laakmann, *supra* note 8; Michael H. Cohen, *A Fixed Star in Health Care Reform: The Emerging Paradigm of Holistic Healing*, 27 ARIZ. ST. L.J. 79 (1995).

215. *See, e.g.*, Hall, *supra* note 7; Hall & Schneider, *supra* note 7; *supra* section II.A.

216. E. Haavi Morreim, *High-Deductible Health Plans: New Twists on Old Challenges from Tort and Contract*, 59 VAND. L. REV. 1207, 1231–32 (2006) (supporting an argument for assumption of risk in the context of cost-constrained treatment by citing judicial concern that physicians would otherwise be required to compel treatment against a patient's wishes); Hall, *supra* note 7, at 178 (describing "informed refusal" as a form of express assumption of risk, and noting that providing care against a patient's informed refusal would constitute battery); Hall & Schneider, *supra* note 7, at 759–60 (noting that courts "caution against liability rules that encourage doctors to coerce or abandon patients").

obvious. Judgments about whether society would be better off if certain unorthodox treatments were available without risk of liability are necessarily subjective.[217] The academic debate about whether allowing patients to negotiate for cost-constrained treatment will make patients better off is just one example, albeit the most well-discussed in the literature.[218] But many other examples abound. Consider, for example, the disputes that might arise in the already-controversial context of reproductive rights. Pro-choice advocates who believe that women suffering medically risky pregnancies should not be deprived of the option to abort will fundamentally disagree with those who believe that patients should be able to choose physicians who provide medical care in accordance with religious directives that limit the availability of abortion in all but the most exceptional cases. A court called upon to decide whether patients in such contexts ought to be able to waive their physicians' duty to provide standard of care treatment will have a difficult time justifying its holding either way.

Similar conflicts are likely to arise when courts are called upon to assess the societal value of any treatments at the edge of responsible medical practice, including those described in section I.B. If courts believe there is some value in allowing patients to seek out experimental cancer therapy involving coffee enemas, how unusual does a treatment need to be before a court is willing to step in to bar a physician's assumption of risk defense when his patient dies prematurely as a result of untreated cancer? In light of the widespread public concern about the dramatically rising costs of health care, would it be reasonable for courts to bind a patient to the consequences of an informed decision to seek out sub-standard care for cost reasons? Given the tragic consequences of botched attempts at self-amputation by patients with apotemnophilia, is there societal value in barring malpractice suits against physicians who perform voluntary amputations on consenting patients, even if those patients later regret their choice? The reasoning in alternative therapy and Jehovah's Witness cases opens the door to similar holdings in other cases of unorthodox treatment—but how far that door opens will depend on societal value judgments that are entirely unpredictable.

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217. *See* Mehlman, *supra* note 7, at 409–10 ("Yet all bargains whereby patients waive legal rights might be said to benefit society, such as by lowering health care costs, which would argue in favor of upholding all waivers, including those outside the experimental context."); Schuck, *supra* note 4, at 912 (the fact that assumption of risk is a jury issue means it is "in reality a culturally constructed and highly normative doctrine, one that is highly responsive to changing social values").

218. *See supra* section II.A.

Thus far, the only clear line that can be drawn based on existing case law is the line distinguishing between unanticipated negligence in the performance of an otherwise standard treatment (whereby such negligence is deemed to have no societal value and deserves no protection) and the offering of treatments outside of the standard of care that pose unique risks but that informed patients nevertheless seek out (which may be societally beneficial in some cases).[219] And while courts have been willing to waive physicians' duty to satisfy the standard of care in alternative treatment and Jehovah's Witness cases, their reasoning provides no clear justification for limiting waivers to those two contexts. Surely, other forms of unconventional treatment that the medical profession deems to be outside standard of care may also provide societal benefits and could likewise be justified using this consequentialist reasoning.

B. Freedom of Choice and Disparities in Bargaining Power

The second argument for rejecting defenses based on a patient's acceptance of risk is that one of elements required for truly voluntary and informed decision-making—freedom of choice—cannot be satisfied in medical contexts. If a patient's decision to explicitly or implicitly assume the risks of treatment is involuntary or unfairly constrained, there are good reasons to bar the use of these defenses. Proponents of this position point out that patients seeking medical treatment typically do so out of necessity, and not out of a desire to satisfy arbitrary personal preferences. They do not choose to be sick and have no alternative to seeking out medical care. Depending on a patient's

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219. An analogy might be drawn here to the distinction drawn by E. Haavi Morreim in the context of physicians who practice under resource constraints imposed by insurance plans. She distinguishes between physicians' "standard of medical expertise," which encompasses the duty to exercise clinical knowledge, skills, and judgment when treating a patient; and their "standard of resource use," which encompasses a duty to advocate for their patients and disclose conflicts of interest when they lack control over resource allocation. *See generally* E. Haavi Morreim, *Medicine Meets Resource Limits: Restructuring the Legal Standard of Care*, 59 U. PITT. L. REV. 1 (1997); E. Haavi Morreim, *Stratified Scarcity: Redefining the Standard of Care*, 17 J. L. MED. & ETHICS 356 (1989). Under Morreim's model, physicians are always obligated to diligently apply their clinical skills and knowledge in treating patients, but they "do not have a presumptive right to distribute other people's money and property without their consent" and so owe no duty to patients to provide all treatments they deem medically necessary. Morreim, *Stratified Scarcity*, *supra*, at 360. Similarly, one might argue for a distinction between the physicians' choice of treatment (though in our case, the choice is based on the patient's request rather than an insurer's resource constraint), and the provision of that treatment in accordance with the standard of skill, knowledge, and diligence expected of reasonable physicians. *See* Hall & Schneider, *supra* note 7, at 771 (distinguishing between resources and skill).

condition, she may be limited to a single treatment option. And in many cases, a patient's choice of providers is limited to the network offered by her insurance company, so she may be unable to "shop around" in the way that consumers of other services can.

From this perspective, it becomes clear why courts have been more willing to accept physician defenses in the alternative treatment and Jehovah's Witness cases.[220] These patients, while driven by medical necessity to seek out treatment, do not seem to be at the same disadvantage as, for example, the patient seeking emergency care in *Tunkl*. In these situations, the patients are not "settling" in their choice of treatment or providers; rather, they are taking affirmative steps to seek out physicians willing to provide treatments that best align with their preferences and values (albeit treatments that arguably fall outside the standard of care).[221] However, beyond the limited contexts of experimental, alternative, and religiously-directed treatment, the same argument could be made any time a patient makes an informed decision to receive her first-choice treatment from a willing provider—in such case, there would likewise seem to be no lack of options, voluntariness, or bargaining power.

The only perspective from which such a decision might be considered unfairly constrained is with respect to the patient's ability to negotiate with her provider for different terms regarding risk allocation. In *Tunkl* and other cases, courts justify their rejection of liability waivers on the grounds that patients seeking medical care are at an inherent bargaining disadvantage, specifically with respect to the opportunity to negotiate for greater legal protection from malpractice.[222] And yet, this concern about patients' lack of bargaining power, so prominent in cases like *Tunkl* and among opponents of contract-based approached to health care, does not seem to cause the same consternation in all contexts. For example, Jehovah's Witnesses, whose religious convictions bar them from receiving blood or blood products, have only two choices when seeking surgical care: receive treatment from a provider who is willing to operate without blood, or forgo surgery entirely. Because surgeons are unlikely

220. *See* Mehlman, *supra* note 7.

221. Kenneth Simons, in a seminal article on assumption of risk doctrine, relies on this distinction. He argues that assumption of risk should be a valid defense in cases of "full preference" (where a plaintiff really does prefer to encounter a defendant's negligence than to pursue a less-risky option) and in cases of "victim insistence on a relationship" (where a plaintiff insists on a relationship with the tortious actor, such relationship primarily benefits the plaintiff, and the defendant either voluntarily chooses to accept the relationship with the plaintiff or has no opportunity to refuse it). Simons, *supra* note 109, at 504–06, 513–17.

222. *See supra* section II.B.2.

to operate on patients committed to refusing blood even in life-threatening circumstances without a release, these patients are effectively forced to sign releases from liability for injuries resulting from blood loss if they want to receive treatment. In this sense, the religious patient's choice to receive medical services in the absence of tort law protections is just as involuntary as the choice of a patient of limited financial means, as in *Tunkl* or *Ash*. One patient is restricted in the treatment she can obtain by virtue of religious belief; the other is restricted by virtue of financial constraints. And yet, courts in Jehovah's Witness cases point to the patient's lack of options as a *justification* for allowing acceptance of risk defenses, rather than an objection. The experimental and alternative treatment cases follow a similar model—courts note that patients who reject mainstream treatment and instead seek out alternative therapy might, in the absence of acceptance of risk defenses, never find providers willing to treat them.[223] Surely, these patients would prefer to retain the right to sue, but in these contexts, courts seem to have no qualms about enforcing releases of liability or accepting assumption of risk as a defense.

In fact, patients seeking out unorthodox care actually seem to be in a *worse* position to bargain for liability protections. In cases like *Tunkl*, where concerns about patients' voluntary choice regularly arise, patients are seeking out high-quality treatment, and wish to retain a remedy if that treatment is performed negligently—an outcome both patient and provider are hoping to avoid. But in the cases discussed in section II.C, arguing that the patients should have the option to retain the right to sue for malpractice seems nonsensical. In these cases, both doctor and patient are committed to a treatment plan that, even if performed as intended, potentially constitutes malpractice. When both parties anticipate the risk that the provider's treatment might be outside the standard of care, there is no world in which the patient could receive this treatment and meaningfully retain the right to sue. In contrast, it is possible to imagine a scenario where a physician offering standard treatment allows a patient to bargain for legal protection in exchange for higher fees, because he believes the chances of his committing unintentional negligence are low.

Perhaps, then, it is this contrast that justifies the differential treatment of these cases. Because physicians offering standard of care treatment

223. *See, e.g.*, Charell v. Gonzalez, 660 N.Y.S.2d 665, 668 (Sup. Ct. 1997) (noting that in the absence of "having the patient execute a comprehensive consent containing appropriate information as to the risks involved," a practitioner of alternative or "non-conventional" medicine could not prevail in a malpractice case).

may vary in their use of waivers of liability, and may be willing to negotiate the shifting of liability risk with patients willing to pay higher fees, there is a risk that permitting waivers of liability in typical malpractice cases might lead to a two-tiered system of medical care. Patients with financial means may be able to negotiate with providers to retain the right to litigate in the event of medical malpractice, while patients who are in desperate need of care or who lack the resources to negotiate with or to select physicians will have no choice but to accept the terms presented to them. Such a stratified system of care, according to many courts, would be unacceptable.[224] In contrast, in the context of unorthodox care that by its very nature likely constitutes negligence and where waivers are effectively a precondition of treatment, no patient is at a disadvantage with respect to any other patient, and there is little potential for stratification based on ability to pay.

This explanation, however, seems unsatisfactory. Courts' language emphasizing the importance of preserving choice and fair opportunities for bargaining when seeking medical care is consistently emphatic and does not seem to distinguish between different treatment contexts. Thus, it would seem odd to conclude that courts only care about patients' lack of bargaining power in contexts where *some* patients have the ability to bargain, but are willing to overlook medical providers' significant bargaining advantage in cases where *all* patients lack bargaining power.

What other explanation might be offered to justify the differential treatment of Jehovah's Witness and alternative therapy cases? It seems that the only real difference is the one highlighted initially—that in these unorthodox treatment cases, patients are receiving their first choice of treatment and providers, whereas in many other contexts patients' choices may be limited by their financial means and insurance coverage. For example, patients seeking treatment at a low-cost clinic because it is the only care they can afford might prefer to go to a top-ranked hospital that does not require a liability waiver, but this choice is not available to them.[225] Thus, setting aside patients' ability (or lack thereof) to bargain for legal protection from malpractice, the typical patient's choice seems less voluntary than the choice of the patient pursuing care outside the

224. *See* section II.B.2.

225. It is worth noting that patients seeking low-cost care at federally qualified health centers are in fact barred, under the Federal Tort Claims Act, from suing the health centers and their employees for injuries suffered as a result of negligent medical care. *About the Federal Tort Claims Act (FTCA)*, HEALTH RES. & SERVS. ADMIN., https://bphc.hrsa.gov/ftca/about/index.html [https://perma.cc/H5CV-XT5J]. However, the patients do retain a right of recovery against the federal government. *Id.*

medical mainstream. As a result, courts might be less willing to bind the typical patient to a contractual waiver or find that she voluntarily assumed the risk of negligent treatment.[226]

The challenge with this distinction is that it rests upon a post facto assessment of the patient's preferences and wishes, and does not lend itself to a bright-line rule. For example, a second patient at the same low-cost clinic may be wealthy but frugal, and eager to save money in exchange for abandoning his right to legal recourse in the unlikely event of malpractice. If this type of bargain is the patient's true preference, then under the model described above he would be permitted to waive his right to sue, but the first patient would not. But it seems very unlikely that a court would be willing to draw such fine distinctions when analyzing the validity of defenses based on a patient's voluntary acceptance of risk.

Thus, while courts consistently highlight the disparity in bargaining power between doctor and patient to justify rejection of waiver and assumption of risk defenses, they do not appear to do so consistently. In Jehovah's Witness and alternative therapy cases, courts are willing to consider these defenses despite the patients' complete lack of bargaining power—and, surprisingly, there appears to be no principled justification for this outcome. Without a clear justification, it is impossible to draw a dividing line between these two contexts and the many others where patients might seek treatment outside the standard of care that would not be available to them if their physicians had no legal protection. The holdings in these cases call into question the widely accepted principle that patients, who as a general rule lack bargaining power as against their medical providers, should retain the right to sue for negligence even when they expressly or implicitly assume the risks of that negligence. Ultimately, the courts' holdings in the Jehovah's Witness and experimental treatment cases seem to suggest that as long as a patient in need of medical care makes an informed decision to seek her first choice of treatment from a willing medical provider, and that treatment inherently falls outside the standard of care, a waiver of liability will be enforceable even if the patient had no opportunity to bargain with her provider for greater protection.

226. This distinction speaks to the concern mentioned in section III.A about unintentional negligence versus intentional negligence.

C. Information Disparity

The final concern raised in cases rejecting contract- and tort-based defenses based on a patient's acceptance of risk speaks to the information disparity between doctor and patient. Proponents of this view note that patients are at an inherent informational disadvantage compared to physicians—not only in terms of understanding the risks and benefits of various treatment options, but also in terms of understanding the likelihood of malpractice and the risks associated with losing legal protection in the event that malpractice does occur.

As to the former concern, which would be fatal to any assumption of risk defense,[227] the foundational principles underlying the doctrine of informed consent effectively negate this argument. Provided the patient is fully informed of the comparative risks and benefits of various treatment options (including those more in keeping with standard medical practices), as is already required by law, the information imbalance between doctor and patient is minimized. Thus, when a patient is actively seeking out treatment that a jury might find to be outside the standard of care—as in the case of experimental treatment or completely bloodless surgery—and her provider has satisfied his legal obligation to disclose the inherent risks and benefits of the requested treatment and its alternatives, there can be no concern that the patient lacks the medical information needed to make a voluntary choice.[228] In contrast, the validity of patient's assumption of risk can be questioned if her physician fails to accurately disclose the inherent risks and benefits of the treatment,[229] or if her physician's negligent conduct results in harms beyond the disclosed inherent risks of treatment.[230]

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227. In contrast, enforcement of a contractual waiver does not require proof of such specific knowledge on the part of the patient.

228. *But see* Mehlman, *supra* note 7, at 391–93 (noting that a physician's disclosure duties under the doctrine of informed consent are narrower than should be required under a doctrine of "fiduciary disclosure").

229. Surprisingly, however, some of the experimental treatment cases have held that a patient may be informed enough to assume the risk of negligent medical treatment even if her physician fails to accurately disclose the inherent risks and benefits of the treatment. In these cases, courts concluded that there was sufficient evidence to support a finding of assumption of risk where patients had independent knowledge of the experimental or alternative therapy, but disclosure by physicians was allegedly lacking. *See supra* note 163. The problems with this approach are discussed in greater detail in section IV.A.1.

230. This distinction aligns with the distinction courts draw between cases where patients intentionally seek out treatment that, if performed as intended, falls outside the standard of care, and those where an otherwise standard treatment is negligently performed. *See supra* section III.A.

The other perspective from which patients might be considered to be at an informational disadvantage as compared to physicians is that some patients might not be aware that, by proceeding with a risky treatment or signing a contractual waiver, they are limiting their right to sue for malpractice.[231] Given that contract law requires exculpatory clauses to be clear and unambiguous, such that the signatory understands the rights she is waiving, a patient's inability to understand the consequences of signing a waiver would be fatal to its enforcement.[232] And yet, this very legitimate concern cannot fully explain the divergent outcomes in the cases discussed herein. In *Tunkl*, for example, the patient signed a document that included the following language:

> RELEASE: The hospital is a nonprofit, charitable institution. In consideration of the hospital and allied services to be rendered and the rates charged therefor, the patient or his legal representative agrees to and hereby releases The Regents of the University of California, and the hospital from any and all liability for the negligent or wrongful acts or omissions of its employees, if the hospital has used due care in selecting its employees.[233]

By any account of contract interpretation, this language seems clear and specific enough to put a signatory on notice of the rights being waived. And yet, despite the satisfaction of the formalities required for exculpatory clauses—and despite the court's deference to the jury's determination that the plaintiff "either knew or should have known the significance of the release"—the court refused to enforce the release on policy grounds.[234] In contrast, some courts in Jehovah's Witness cases have carefully evaluated the precision and specificity of contractual language in order to reach decisions as to the enforceability of a waiver. In *Garcia*, for example, the court held that a release signed by a Jehovah's Witness patient that "explicitly delineated the desires and

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231. Some authors suggest that this problem might be solved by requiring fiduciary standards of disclosure regarding the legal consequences of a patient's choice to proceed with risky treatment. *See, e.g.*, Mehlman, *supra* note 7, at 383 (suggesting that a fiduciary disclosure model would require disclosure of information regarding "allocation of risk").

232. The tort defense of assumption of risk, in contrast, does not require knowledge on the part of the patient that proceeding with treatment with knowledge of its risks might bar recovery if those risks manifest themselves—assumption of risk is implied by behavior.

233. Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 442 (Cal. 1963).

234. In a footnote, the court noted that at the time the plaintiff signed the release, he "was in great pain, under sedation, and probably unable to read." *Id.* at 442 n.1. However, the court did not overturn the jury's finding that the plaintiff "either knew or should have known the significance of the release." *Id.*

intentions of both parties" barred the patient's suit as a matter of law.[235] But in *Corlett*, the court held that a similar release of liability for surgery without blood did not bar a malpractice suit, because the language of the release did not specifically relieve physician from liability for negligence in diagnosis and treatment.[236]

Thus, while the disparity in understanding between doctor and patient as to the legal implications of a decision to proceed with treatment may certainly justify non-enforcement of contractual releases that lack the appropriate language,[237] decisions in cases like *Tunkl* show that correction of this informational disparity is not sufficient to save such releases.

The experimental treatment, alternative treatment, and Jehovah's Witness cases, then, seem to establish that as long as a patient is informed of the risks and benefits of the various treatment options (whether by way of an informed consent conversation with the physician or through the patient's independent knowledge), and as long as any contractual language waiving liability is sufficiently precise, there is no meaningful informational disadvantage that would bar the use of tort or contract defenses based on voluntary acceptance of risk where the patient suffers injury as a result of a risk inherent in a medical procedure—even if the physician violated the standard of care by offering that procedure.

IV. CAUTIONS AND CHALLENGES

Part III reconsidered the "exceptional" alternative treatment and Jehovah's Witness cases in light of the three traditional objections to the use of contract- and tort-based defenses based on a patient's voluntary acceptance of risk. It concluded that while there are good reasons for courts to treat these cases differently from typical cases of medical malpractice, those reasons would likewise be applicable to many other

235. Garcia v. Edgewater Hosp., 613 N.E.2d 1243, 1251 (Ill. App. Ct. 1993).

236. Corlett v. Caserta, 562 N.E.2d 257 (Ill. App. Ct. 1990).

237. *See, e.g.*, Schneider v. Revici, 817 F.2d 987 (2d Cir. 1987) (finding that the covenant not to sue in the consent form signed by the patient was unenforceable due to lack of precision); Abramowitz v. N.Y. Univ. Dental Ctr., Coll. of Dentistry, 494 N.Y.S.2d 721, 724 (App. Div. 1985) (rejecting an exculpatory clause on the grounds that the contractual language did not "unmistakenly express an intention on the part of the plaintiff to absolve the defendant of liability for its own negligence"); Poag v. Atkins, 806 N.Y.S.2d 448, 2005 WL 2219689, at *3 (Sup. Ct. Sept. 12, 2005) (unpublished table decision) (rejecting exculpatory agreement in a medical malpractice case because "no separate heading or caption was present to alert the decedent that she was foregoing the right to bring suit").

contexts in which patients knowingly and voluntarily pursue unorthodox and potentially negligent treatment.

First, these cases demonstrate that the physician's duty to provide treatment in accordance with the standard of care is by no means absolute. Where judges or juries believe that the non-standard treatment serves greater societal interests not recognized by a strict interpretation of the medical community's standards, they are willing to waive a physician's duty to comply with the standard of care (or at least limit liability to some degree).

Second, despite courts' and commentators' insistence that patients should not be able to waive their right to sue because of their bargaining disadvantage with respect to medical providers, the alternative treatment and Jehovah's Witness cases belie this notion. Even in situations where physicians would flatly refuse to provide treatment to patients with life-threatening illnesses in the absence of liability protection, courts have been willing to recognize some patients' decisions to explicitly or implicitly waive their right to sue.

Finally, while the information disparity between doctor and patient is certainly a concern, these cases demonstrate that it is possible for a patient to be informed enough to voluntarily assume the risk of negligent medical treatment. If the medical risks and injuries that manifest themselves are those inherent in the requested treatment—where that treatment, even if performed as intended, falls outside the standard of care—then a patient's informed consent to treatment effectively serves as a defense to liability. And some cases, surprisingly, found sufficient evidence of assumption of risk even where disclosure by physicians was allegedly lacking, but patients possessed independent knowledge of the risks of treatment.

Based on these precedents, we can conclude that beyond the contexts of patients seeking experimental, alternative, or religiously-directed treatment, courts have good reason to be receptive to contract- and tort-based defenses when patients knowingly and voluntarily seek out treatment that falls outside the standard of care, as long as: (a) patients are fully informed of the treatment's medical risks and benefits, as well as the risks and benefits of alternative available treatments; (b) the treatment is performed in accordance with expectations, such that the risks that ultimately arise are those inherent in the treatment—that is, not caused by unanticipated error in the performance or administration of the treatment; and (c) the legal factfinder believes there is some societal

value in having this treatment available, even if the medical community as a whole rejects it.[238]

A. Additional Requirements for Patient Protection

As a descriptive matter, the cases discussed in this Article support the use of contract- and tort-based defenses in medical malpractice cases upon the satisfaction of the above three conditions. Normatively, however, I argue that additional conditions ought to be imposed to strengthen protections for patients, particularly with respect to ensuring that a patient's consent is fully informed and voluntary.

1. Satisfaction of Physician's Informed Consent Duties

The most concerning conclusion in at least some of these cases is the suggestion that a patient might be deemed informed enough to assume the risk of treatment *even if* her physician did not fully inform her of the risks of treatment.

In *Charell*, for example, the court found sufficient evidence to support an informed consent claim where the physician told his patient that an alternative therapy had a 75% success rate, failed to disclose that he was not an oncologist, failed to inform her that the treatment was experimental and not generally accepted among physicians, and failed to provide information about the risks of and alternatives to the treatment protocol.[239] Nevertheless, the court upheld the jury's finding that the plaintiff impliedly assumed the risk of treatment, noting that the patient had sufficient knowledge of the risks of treatment from sources other than her physician.[240] The court pointed out that the plaintiff was "a well-educated person who . . . did a significant amount of investigation regarding the treatment being offered by defendant and hence became quite knowledgeable on the subject."[241] Similarly, in *Poag*, the physician allegedly assured the patient that an alternative treatment involving vitamins and antioxidants could "definitely cure" her breast cancer, and did not inform her that the treatment protocol was experimental and

238. It is this final requirement that poses the greatest challenge in any efforts to predict the outcome of cases where patients are harmed as a result of unorthodox treatments like those described in section I.B. There is simply no accounting for judges' and jurors' varying perspectives on the value of such treatments to society. *See* discussion *supra* section III.A.

239. Charell v. Gonzalez, 660 N.Y.S.2d 665, 668 (Sup. Ct. 1997).

240. *Id.* at 669.

241. *Id.*

considered unsafe by some medical groups.[242] Nevertheless, the court concluded that there was a triable issue of fact as to what risks the plaintiff was actually informed of and whether she impliedly assumed these risks.[243]

It is troubling to think that a physician might benefit from defenses based on a patient's acceptance of risk despite having breached his duty to inform the patient of the risks of treatment and its alternatives. Nevertheless—and perhaps surprisingly—it is not doctrinally illogical. As Mehlman notes, pure applications of contract and tort law do not effectively account for the fiduciary nature of the doctor-patient relationship.[244] The traditional tort defense of assumption of risk, for example, requires only that a plaintiff voluntarily choose to encounter known risks—it does not speak to how the plaintiff obtains knowledge of these risks. Contract law, of course, imposes greater disclosure duties on defendants, by requiring that the contractual language in liability waivers (typically drafted by defendants) specifically define the scope of risk the plaintiff is assuming. However, neither contract nor tort defenses impose a non-delegable duty[245] on the defendant to communicate—in detail and in person—both the risks and benefits of the encounter the plaintiff is choosing to pursue, and the risks and benefits of alternative options the plaintiff might choose.[246] Thus, in a case like *Charrell*, a

242. *Poag*, 806 N.Y.S.2d 448, 2005 WL 2219689, at *1 (unpublished table decision).

243. *Id.*

244. *See generally* Mehlman, *supra* note 7.

245. The physician's duty to obtain a patient's informed consent is widely viewed as a duty that cannot be delegated to others. *See, e.g.*, Robert Gatter, *The Mysterious Survival of the Policy Against Informed Consent Liability for Hospitals*, 81 NOTRE DAME L. REV. 1203, 1205 (2006) (noting that "established law . . . presumes that control over—and, consequently, responsibility for—informed consent should reside exclusively with physicians"); Shinal v. Toms, 162 A.3d 429, 453–54 (Pa. 2017) (holding that under Pennsylvania's informed consent statute, the duty to secure a patient's informed consent rests exclusively with the physician and cannot be delegated).

246. Moreover, some scholars suggest that the enforcement of waivers of liability ought not be conditioned on proof of an informed consent-type disclosure conversation. For example, Hall and Schneider—in arguing that patients' refusals of standard care for cost reasons should be treated as an issue of contract (rather than tort)—conclude that the law "should not require special evidence or proof of informed refusal, assumption of risk, or waiver of liability" when evaluating a patient's contractual refusal, provided there is no fraud or misrepresentation on the physician's part. Hall & Schneider, *supra* note 7, at 775. Hall and Schneider justify their position by noting that when patients refuse recommended care, physicians already "have incentives to convince patients to say yes," and that therefore "the law need not scrutinize how vigorously they did so." *Id.* In arguing against "full-bore informed consent" for patient refusals of costly treatment, Hall and Schneider seem to distinguish refusals of treatment from consent to treatment. *Id.* I find this distinction untenable. When a patient refuses the standard of care treatment and opts for a less-costly alternative, there are elements of both refusal and consent. Unless the patient is refusing any treatment, she will have to provide consent for the treatment she ultimately chooses—and as a legal

patient might be limited in her right of recovery for medical malpractice, while still retaining an independent right to recover for an informed consent violation.[247]

I posit, however, that a physician's legal duties under the doctrine of informed consent should not be disentangled from his right to raise a defense when a patient chooses an unorthodox treatment that may constitute medical malpractice. Allowing physicians to benefit from defenses based on a patient's voluntary acceptance of risk when they have not fully informed their patients of the risks of treatment—while perhaps permissible under pure doctrines of contractual waiver and assumption of risk—is fundamentally inconsistent with the medical profession's legal and ethical duties of disclosure. To meaningfully protect patients' interests in such cases, physicians should be able to rely on contract- and tort-based defenses only if they satisfy their obligation to secure the patient's informed consent to treatment.

Of course, some might argue that conditioning malpractice defenses on satisfaction of the physician's informed consent obligations is insufficiently protective of patient interests. The idea that a patient's informed consent to negligent treatment might effectively constitute an assumption of risk is in itself highly controversial.[248] This is because the legal and ethical doctrines of informed consent are fundamentally tools for patient protection—they grant patients a right to receive information from their physicians that furthers their ability to make autonomous decisions, and allow patients to recover damages if their physicians do not satisfy their disclosure obligations. Assumption of risk and waiver of liability, in contrast, are tools for physician protection—they grant patients no rights and operate only to reduce patients' ability to recover damages. Thus, some might argue that it is unfair to tie these two doctrines together at all—that a rights-conferring doctrine (informed consent) should never be used in a way that reduces or eliminates a plaintiff's legal remedies.

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matter, this requires the physician to disclose the risks and benefits of the various treatment options, including the standard of care the patient has refused.

247. This would be one rare context in which the common criticism that informed consent and malpractice actions are redundant would not apply. *See* Hall et al., *supra* note 113, at 431 (noting that where a claim for informed consent "overlaps with ordinary malpractice, . . . it is mostly redundant" because deviation from the customary standard of care constitutes negligence, "regardless of the presence or absence of consent").

248. *See, e.g.*, Elizabeth Sepper, Making Religion Transparent 10 (2017) (unpublished manuscript) (on file with author) (referring critically to the idea that informed consent might be treated as an assumption of risk in the context of health care providers' religious refusals to provide treatment).

While there is certainly merit to this position, I believe that it does not account for the true richness of the principle of patient autonomy. Respecting a competent person's autonomous decision sometimes means allowing that person to make a choice that others think is unreasonable. And while many critics have argued that the pendulum of medical practice has swung too far in the direction of patient autonomy at the expense of other important ethical principles (like justice and beneficence),[249] that argument does not speak to the precise issue addressed in this Article. Certainly, in some exceptional cases, one might opt to balance the values of beneficence and autonomy in such a way that would justify overriding a patient's informed decision and imposing treatment against the patient's will. But if a patient has already made a decision and acted upon it, the opportunity to protect the patient from making a poor choice has already passed—the balance of values has already been struck. If we value autonomy enough to permit patients to make such choices without interference by state actors or medical professionals, then it seems incongruous to justify retroactively freeing these patients from the consequences of their informed and autonomous choices.[250]

2. Addressing Physician Influence

Another question to consider in developing a more patient-protective approach is whether a physician's recommendation might be so influential that it would effectively render the patient's treatment decision non-autonomous. As a result of the power dynamic inherent in the physician-patient relationship, physicians have significant ability to influence patient decision-making. That is, even if two physicians present identical facts about treatment options, their recommendations as to treatment, or the way in which they frame those facts, may sway a patient's decision.[251] Given how much a physician's own perspective

249. *See, e.g.*, Moulton & King, *supra* note 26, at 88 (discussing criticism of "a decision-making model that relies entirely on patient autonomy"); Quill & Brody, *supra* note 19, at 764 (arguing that misunderstanding about what it means to respect patient autonomy has led physicians to neglect their duties to advise patients).

250. Taking this approach would treat a patient's informed agreement to receive treatment from a physician as a type of voidable contract. Typically, contracts are only voidable if they are made under conditions of coercion, fraud, or minority. *See generally* WILLISTON ON CONTRACTS, *supra* note 96, § 1:20.

251. *See generally* Judith Covey, *A Meta-Analysis of the Effects of Presenting Treatment Benefits in Different Formats*, 27 MED. DECISION MAKING 638 (2007); Theresa M. Marteau, *Framing of Information: Its Influence on Decisions of Doctors and Patients*, 28 BRITISH J. SOC. PSYCHOL. 89 (1989).

can influence his patients' decisions, there is a concern that the "voluntariness" required for a patient to effectively assume a risk (whether implicitly or by way of contract) may be compromised.

To a certain extent, this is an unavoidable problem. Every decision a person makes is based on innumerable factors and influences. Claiming that a person's decision is non-autonomous simply because it has been influenced by another's perspective is a difficult argument to defend. Furthermore, principles of medical ethics explicitly acknowledge that physicians *do* have a role in advising patients, and that complete neutrality in conveying factual information without any acknowledgment of values neglects important aspects of the physician's fiduciary obligations.[252]

In the types of cases described in this Article, moreover, patients are often the ones driving medical decision-making—sometimes over their physicians' initial objections. In such cases, there is little opportunity for undue physician influence. For example, a Jehovah's Witness patient whose religious convictions bar the use of blood products is unlikely to be swayed by any recommendation to transfuse blood. While a patient whose values are not quite so absolute, such as a patient who prefers alternative therapy to conventional treatment, is perhaps more likely to be affected by a physician's recommendation, such patients often choose their physicians specifically because they are willing to offer treatments that align with the patient's values.[253] Thus, one could argue that physicians should be able to benefit from assumption of risk-based defenses only if the patient's commitment to an unorthodox treatment is so fixed that the physician has little ability to influence the patient's decision. This, however, is an extremely fact-sensitive determination (and one that is, moreover, subject to significant hindsight bias), so it is unlikely that courts would be willing to recognize the patient's motivation as a factor in adjudicating malpractice cases.

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252. *See generally* Ezekiel J. Emanuel & Linda L. Emanuel, *Four Models of the Physician-Patient Relationship*, 267 JAMA 2221 (1992); Moulton & King, *supra* note 26; Quill and Brody, *supra* note 19.

253. In *Poag v. Atkins* and *Schneider v. Revici*, for example, the patients sought out Drs. Atkins and Revici after hearing them speak on radio programs about the benefits of alternative treatment. Schneider v. Revici, 817 F.2d 987, 989 (2d Cir. 1987); Poag v. Atkins, 806 N.Y.S.2d 448, 2005 WL 2219689, at *1 (Sup. Ct. Sept. 12, 2005) (unpublished table decision). In *Charell*, the patient pursued alternative treatment with Dr. Gonzales, whom she knew about through his tapes and lectures, because she had "witnessed the severe discomfort experienced by a relative who had undertaken chemotherapy and radiation." Charell v. Gonzalez, 660 N.Y.S.2d 665, 666 (Sup. Ct. 1997).

A more practical way of addressing issues of physician influence is to consider whether the physician had any clear conflicts of interest in making a treatment recommendation (besides the obvious financial benefit inherent in providing medical treatment in exchange for payment). There is precedent suggesting that physicians have a legal obligation to disclose financial conflicts of interest that may influence their treatment decisions. In *Moore v. Regents, University of California*,[254] a case in which a physician provided unnecessary medical services to a patient without disclosing his own financial incentives in commercial development of a cell line from the patient's blood, the California Supreme Court held that "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."[255] In a number of malpractice cases against physicians whose medical recommendations were influenced by HMO financial incentives, courts also recognized that a physician's failure to disclose financial incentives might constitute a breach of duty.[256]

Thus, one additional mechanism for patient protection would be to allow physicians to rely on these defenses only if they have disclosed to the patient any personal conflicts of interest that might affect their treatment recommendations. As noted above, this is already a requirement for the satisfaction of the physician's informed consent duties under common law. Thus, this recommendation would follow neatly from the recommendation presented above that physicians' use of these defenses be conditioned on the satisfaction of their common law duty to obtain a patient's informed consent.[257]

Patient advocates, however, might argue that disclosure of conflicts of interest is insufficient to protect patients from undue physician influence.

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254. 793 P.2d 479 (Cal. 1990).

255. *Id.* at 485.

256. Shea v. Eisensten, 208 F.3d 712, 717 (8th Cir. 2000) (holding that a jury could find physicians liable for negligent misrepresentation for failing to disclose a financial incentive to avoid referrals, where this failure to disclose prevented the plaintiff "from making an informed choice of whether to seek what might have been a life-saving referral at his own expense"); Neade v. Portes, 739 N.E.2d. 496, 502–03 (Ill. 2000) (finding that a fiduciary duty claim for failure to disclose financial incentives was duplicative of the medical malpractice claim); DAB v. Brown, 570 N.W.2d 168, 171 (Minn. Ct. App. 1997) (holding that a physician's failure to disclose a kickback scheme "presents a classic informed consent issue"); *see generally* Nadia N. Sawicki, *Modernizing Informed Consent*, 2016 U. ILL. L. REV. 821, 842.

257. *See supra* section IV.A.1.

Rather, perhaps physicians with financial conflicts of interest ought to be barred entirely from reliance on assumption of risk and waiver defenses, even if their conflicts have been disclosed. I believe that this approach, however, goes one step too far. As explained above,[258] so long as we are willing to allow patients to choose treatment options in which their physicians have financial interests, there is no reason to permit those patients, under ordinary circumstances, to seek legal recovery for the consequences of their informed and voluntary decisions.

3. Disclosure of Deviations from the Standard of Care

While the requirement that physicians fully inform their patients about the risks and benefits of a selected treatment and its alternatives would be sufficient to satisfy legal standards of informed consent, it may overlook other ways in which patients' decisions might not be fully informed or autonomous. Imagine, for example, a patient who chooses to accept a treatment with a 10% chance of success without knowing that the treatment falls outside the standard of care (and therefore, that the physician's provision of this treatment constitutes malpractice). In such a case, the patient might allege that had she known the treatment was outside the standard of care, she would not have pursued it. In other words, she would only have been willing to accept a treatment with a 10% chance of success had she known that the treatment was within the professional standard of care.

However, it is by no means clear that a traditional informed consent claim on these grounds—where the claim rests on a lack of disclosure as to whether the proposed treatment is within the standard of care—would be successful. While there is no case law on this precise issue, courts in other contexts have held that a regulatory body's approval of a treatment is not a "material risk" that must be disclosed under the common law of informed consent.[259] Numerous cases dealing with off-label use of drugs

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258. *Id.*

259. *In re* Orthopedic Bone Screw Prod. Liab. Litig., No. 1014, 1996 WL 107556, at *5 (E.D. Pa. Mar. 8, 1996) (holding that a physician cannot be liable under informed consent "for failing to advise a patient that a particular device has been given an administrative or regulatory label by the FDA"); *see also, e.g.*, Alvarez v. Smith, 714 So. 2d 652, 654 (Fla. Dist. Ct. App. 1998) (holding that the FDA status of metal screws used in plaintiff's spinal surgery was not a "medical risk" that must be disclosed as part of informed consent); Blazoski v. Cook, 787 A.2d 910, 919 (N.J. Super. Ct. App. Div. 2002) (holding that because FDA regulatory status "do[es] not speak directly to the medical issues surrounding a particular surgery" it need not be disclosed as part of informed consent); Klein v. Biscup, 673 N.E.2d 225, 231 (Ohio Ct. App. 1996) (holding that "off-label use of a medical device is not a material risk" that must be disclosed as part of the informed consent process); Southard v. Temple Univ. Hosp., 781 A.2d 101, 107 (Pa. 2001) (holding that because

and devices—that is, the use of FDA-approved drugs and devices for a purpose outside the scope of the FDA's approval—have concluded that physicians have no duty to disclose to patients that the treatments they are providing are not FDA-approved for a particular purpose.[260] That said, many off-label uses are, in fact, within the standard of care. In contrast, use of a drug or device that has not been approved by the FDA as safe and effective for *any* purpose—which likely would constitute malpractice outside the context of clinical research—could potentially be viewed as material to a patient's treatment decision and therefore within the scope of informed consent.

But even if a treatment's deviation from the standard of care is not within the traditional scope of informed consent disclosure, there is an argument to be made that a physician's reliance on assumption of risk as a defense—which requires a plaintiff's voluntary choice to encounter a known risk—requires proof that the plaintiff knew the physician would be deviating from the standard of care.

Unfortunately, the assumption of risk jurisprudence regarding this issue is unclear. Secondary assumption of risk requires a showing that the plaintiff voluntarily encountered a known risk of the defendant's negligence. But there is no doctrinal guidance as to whether the knowledge requirement is satisfied when the plaintiff is aware of the risks of proceeding with an activity (i.e., a particular type of physical injury), or whether it requires the more specific knowledge that these risks exist only as a result of a breach of duty by the defendant.

Nevertheless, a hypothetical should demonstrate that knowledge of a defendant's breach cannot be a legal requirement for secondary implied assumption of risk, as long as the plaintiff is aware of the specific risks

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FDA labeling "does not constitute a material fact, risk, complication or alternative to a surgical procedure," it need not be disclosed as part of the informed consent process). *But see* Corrigan v. Methodist Hosp., 869 F. Supp. 1202, 1207 (E.D. Pa. 1994) (holding that allegations that a doctor failed to disclose the "investigational" status of bone screws used in plaintiff's surgery raised a triable issue of fact as to informed consent); Corrigan v. Methodist Hosp., 874 F. Supp. 657, 659 (E.D. Pa. 1995) (same). *See also* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71 (1998) (collecting cases on this issue and concluding that "[b]ecause FDA regulatory status of medical devices and drugs is irrelevant to the nature, risks, benefits, or alternatives of medical procedures, there is and should be no legal or ethical obligation for physicians to discuss FDA regulatory status issues with their patients").

260. *See supra* note 259. However, some commentators disagree with this outcome. One article notes that "[t]he view that off-label status is not material to a patient's decision to accept a particular course of treatment is rationalized on the wobbly ground that off-label status is a regulatory fact, not a medical fact, and thus that it does 'not speak directly to the medical issues surrounding a particular [use].'" Philip M. Rosoff & Doriane Lambelet Coleman, *The Case for Legal Regulation of Physicians' Off-Label Prescribing*, 86 NOTRE DAME L. REV. 649, 672 (2011).

he is encountering. Imagine, for example, a skier who encounters a trail that is not smoothed or well-packed, and is covered with large chunks of ice. The skier should understand that skiing down this dangerous trail poses additional risks beyond the inherent risks in skiing a well-maintained trail, and so can be said to have assumed these additional risks if he chooses to proceed. However, the skier may not know whether the condition of the trail is due to the trail operator's negligence. For example, the trail's condition may be the result of an avalanche that occurred seconds ago; if no reasonable facility operator would have been able to correct the condition or provide a warning in that brief time, then the skier would not be able to recover because there was no breach of duty ("primary assumption of risk"). But if, unbeknownst to the plaintiff, the condition of the trail was due to negligent maintenance by the facility operator, it would seem odd to bar the use of secondary assumption of risk as a defense simply because the plaintiff did not know that the additional risks she was encountering were the result of a breach of duty. A dangerous trail is dangerous regardless of whether the danger was caused by natural and unavoidable conditions or by a defendant's negligence. Holding that a plaintiff should be able to recover in full when the plaintiff encounters a danger without knowing it was caused by a defendant's negligence—despite the plaintiff's knowledge, awareness, and voluntary acceptance of the dangerous condition itself—seems inconsistent with the principles underlying the doctrine of assumption of risk.

Applying this reasoning to the medical context, there seems to be no doctrinal reason to bar the use of implied or express assumption of risk as a defense when a patient chooses to proceed with a treatment with the understanding that it poses specific risks, simply on the grounds that the patient did not know that the physician's provision of that treatment was itself a breach of duty.

But as with the informed consent requirements discussed in section IV.A.1, the fact that the tort doctrine of assumption of risk does not require specific knowledge of a defendant's breach may have troubling implications in the context of medical treatment. As noted above, pure applications of contract and tort law do not account for the fiduciary aspects of the doctor-patient relationship, and there are policy reasons why we might impose additional requirements on physicians claiming these defenses—as compared to widget manufacturers, for example. The arguments for imposing a requirement that physicians disclose their deviations from the standard of care would be similar to those for imposing such a disclosure duty under informed consent law—that patients, more so than plaintiffs in non-medical contexts, are at an

informational disadvantage as compared to defendant physicians. The common law of informed consent (requiring disclosure of the risks and benefits of various treatment options that would be material to a patient's decision) developed in order to correct this informational imbalance. But surely a patient cannot make a fully informed and voluntary decision about whether to proceed with a risky treatment if she does not know that the treatment falls outside the standard of care and has been rejected by the medical community.

Thus, although common law may not currently require that physicians disclose deviations from the standard of care (whether to satisfy their informed consent duties or benefit from assumption of risk-based defenses), there are strong policy arguments for requiring such disclosure. The expansion of assumption of risk and contractual waiver defenses to a broader set of medical contexts should be tied to additional patient protections—here, a requirement that physicians who wish to protect themselves from liability when their patients choose medical malpractice must first disclose that the chosen treatment is a deviation from the standard of care.

B. Ensuring Responsible Medical Practice

Proponents of the traditional patient-protective view will argue against expanding recognition of assumption of risk defenses beyond alternative treatment and Jehovah's Witness cases to other instances of unorthodox patient-directed care. Once patients are no longer permitted to sue for injuries resulting from treatment that the medical and legal communities consider to be outside the standard of care, critics will argue, the deterrent effects of tort law disappear.[261] Physicians will have no incentive to practice according to medical norms, and patients will be increasingly exposed to treatment methods that pose significant risks of harm. Such an outcome would effectively render the medical and legal concepts of "standard of care" obsolete.

It is true that limiting malpractice liability for physicians who choose to offer patients non-standard treatments will remove an important disincentive to negligent medical practice. However, these effects will be limited to the intentional provision of treatment outside of the standard of care with a patient's voluntary and informed consent. This establishes a very clear dividing line and will not impact patients' right

261. *See, e.g.*, Arlen, *supra* note 90, at 257 (arguing against contractual limitations on patients' right to sue for medical malpractice, on the grounds that the use of such contracts would defeat the individual and systemic deterrent effects of tort law).

to tort recovery for the kind of unanticipated negligence that forms the basis of many medical malpractice actions, which by its very nature patients cannot knowingly accept.

Furthermore, it is important to recognize that while malpractice liability incentivizes quality of care at both the individual and systemic level,[262] a fundamental and unique goal of tort law is to allow victims of civil wrongs to obtain recourse against those who have caused their injuries.[263] And there is no inconsistency in holding that a patient should not receive compensation for injuries from a non-standard treatment he knowingly and voluntarily consented to, while also holding that a physician who provides such treatment is violating the norms of the medical profession (and therefore would be considered to have breached a duty had his patient not accepted the risks of treatment). Tort law, of course, is also driven by the desire to incentivize good behavior and deter people from taking unreasonable risks that impact third parties. However, this goal is not unique to the tort system—it is shared by criminal law, administrative law, and various other societal levers for controlling behavior. Thus, because there are many other legal and practical mechanisms beyond the bounds of tort law that serve to reinforce standards of care and incentivize physicians to practice within those standards, limiting patients' ability to recover in tort when they choose medical malpractice is unlikely to increase the market in "bad medicine."

1. State Licensure and Discipline

The most valuable legal mechanisms in this regard are state medical licensure and discipline laws, which establish the requirements for obtaining and retaining a medical license, and authorize state medical boards to discipline physicians whose practices falls too far outside the medical mainstream. Indeed, Dr. Emanuel Revici, the defendant in *Schneider v. Revici*[264] and *Boyle v. Revici*, [265] lost his medical license as a result of his treatment of cancer patients with alternative therapies.[266]

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262. *Id.* (discussing systemic incentives provided by tort law in malpractice cases).

263. JOHN C.P. GOLDBERG & BENJAMIN C. ZIPURSKY, THE OXFORD INTRODUCTION TO U.S. LAW: TORTS 6 (2010) ("Tort law empowers victims to obtain recourse against those who have wronged them.").

264. 817 F.2d 987 (2d Cir. 1987).

265. 961 F.2d 1060 (2d Cir. 1992).

266. Revici v. Comm'r of Educ., 546 N.Y.S.2d 240 (App. Div. 1989) (upholding Commissioner of Education's disciplinary action against Dr. Revici for treating breast cancer patients with vinegar, baking soda, soft boiled eggs, and coffee); Emanuel Revici, M.D., Arb. 93-128, 1993 WL 13670584

Countless examples have been reported in the media of disciplinary actions against "maverick" physicians providing unorthodox treatments sought out by patients skeptical of traditional medical practices, including treatment of "chronic" Lyme disease with long-term antibiotic therapy,[267] delaying or denying routine pediatric vaccinations,[268] stem cell treatments for both anti-aging purposes and treatment of serious disorders,[269] treatment of autistic children with chelation therapy and chemical castration,[270] in vitro implantation of multiple embryos,[271]

(N.Y. Dep't of Health Bd. for Prof. Med. Conduct Jan.1, 1993) (sustaining Hearing Committee's Determination revoking Dr. Revici's license to practice medicine in New York State).

267. Holcomb B. Noble, *Lyme Doctors Rally Behind a Colleague Under Inquiry*, N.Y. TIMES (Nov. 10, 2000), https://www.nytimes.com/2000/11/10/us/lyme-doctors-rally-behind-a-colleague-under-inquiry.html [https://perma.cc/XF49-EGHA] (discussing controversy surrounding board discipline of physicians treating Lyme disease); David Whelan, *Lyme Inc.*, FORBES (Feb. 23, 2007), https://www.forbes.com/forbes/2007/0312/096.html [https://perma.cc/863M-7WNL] (describing medical board action against "Lyme Literate" physician Dr. Joseph Jemsek).

268. Arthur L. Caplan, *Revoke the License of Any Doctor Who Opposes Vaccination*, WASH. POST (Feb. 6, 2015), https://www.washingtonpost.com/opinions/revoke-the-license-of-any-doctor-who-opposes-vaccination/2015/02/06/11a05e50-ad7f-11e4-9c91-e9d2f9fde644_story.html?utm_term=.63250c5dff31 [https://perma.cc/JJ2A-3FB6] (arguing that doctors who oppose vaccination should have their medical licenses revoked, and that state licensing boards have the authority to do so); Matt Hamilton, *Dr. Bob Sears, Critic of Vaccine Laws, Could Lose License After Exempting Toddler*, L.A. TIMES (Sept. 8, 2016, 10:20 PM), http://www.latimes.com/local/lanow/la-me-ln-oc-vaccine-doctor-20160908-snap-story.html [https://perma.cc/87JA-FDQS] (describing disciplinary action against physician for "improperly excusing a toddler from immunization" on the basis of a parent's description of the child's response to previous vaccinations).

269. Alan Zarembo, *Doctor with Revoked License Continues to Sell Unproven Stem Cell Treatments*, L.A. TIMES (May 16, 2015, 5:25 PM), http://www.latimes.com/local/california/la-me-stem-cell-injections-20150517-story.html [https://perma.cc/PV3H-E75U] (describing disciplinary action against physician who used stem cell injections to treat patients with arthritis, muscular dystrophy, spinal cord injuries and other conditions).

270. Deborah Shelton, *Dr. Mark Geier Loses License in Illinois, Missouri*, CHI. TRIB. (Nov. 5, 2012), http://articles.chicagotribune.com/2012-11-05/news/ct-met-autism-doctor-20121106_1_autism-doctor-david-geier-mark-geier [https://perma.cc/S4GU-PYV6] (describing disciplinary action against physician using "dubious treatments" for autism); Trine Tsouderos & Patricia Callahan, *Risky Alternative Therapies for Autism Have Little Basis in Science*, CHI. TRIB. (Nov. 22, 2009), http://www.chicagotribune.com/lifestyles/health/chi-autism-treatments-nov22-story.html [https://perma.cc/T8GB-CFAX] (describing complaints to state medical boards filed by parents of children with autism who received "alternative" therapies).

271. Shaya Tayefe Mohajer, *State Medical Board Revokes Octomom Doc's License*, SAN DIEGO UNION-TRIB. (June 2, 2011, 1:58 AM), http://www.sandiegouniontribune.com/sdut-state-medical-board-revokes-octomom-docs-license-2011jun02-story.html [https://perma.cc/N664-78LN] (describing Medical Board of California's decision to revoke license of physician who implanted twelve embryos in Nadya Suleman, the "Octomom"); Shaya Tayefe Mohajer, *FDA Witness: Octomom Doc Used Experimental Methods*, 89.3KPCC (Nov. 18, 2010), http://www.scpr.org/news/2010/11/18/21094/fda-witness-octomom-doc-used-experimental-methods/ [https://perma.cc/QGW3-9YKP] (describing evidence in state medical board hearing for Nadya Suleman's physician, including evidence that Dr. Kamrava went "out of his way to warn Suleman of the risks of implanting all 12 embryos," and "clearly spelled out over and over and over again that . . . he

unnecessary tests and inappropriate prescribing,[272] recommendation of medical marijuana,[273] and aid in dying for non-terminal patients.[274] While some physicians who engage in these non-standard practices view board discipline as a badge of honor reflecting their status as innovators,[275] the threat of suspension or complete revocation of one's medical license for practicing outside the standard of care surely has a deterrent effect even greater than that of tort liability.

2. Insurance Reimbursement

A second mechanism that can be relied upon to address concerns about quality of care is that of insurance reimbursement. Even if the threat of tort liability for unorthodox treatments is gone, physicians will not provide these treatments if they know they will not be compensated for their services. Both governmental and private insurers already use financial levers to drive medical practice—from utilization review of high-cost procedures[276] to coverage refusals for specific conditions and

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disagreed with her decision, and that she understands everything, that she's insisting he transfer all the embryos").

272. Tara Bannow, *Redmond Physician Could Lose Her License*, BEND BULL. (May 30, 2015, 12:04 AM), http://www.bendbulletin.com/newsroomstafflist/3203851-151/redmond-physician-could-lose-her-license [https://perma.cc/R9ZC-TSCZ] (discussing board investigation of a physician for a "'pattern' of unnecessary tests, treatments that were not medically indicated and prescribing excessive amounts of antibiotic and opioid medications").

273. Felice J. Freyer & Kay Lazar, *Medical Marijuana Doctor Loses License to Practice*, BOS. GLOBE (June 3, 2016), https://www.bostonglobe.com/metro/2016/06/03/medical-marijuana-doctors-loses-license-practice/L5jRBrby55bFWb8p8AwB6I/story.html [https://perma.cc/M8AP-K2R6] (describing medical board's revocation of licenses of two physicians for "improperly certifying that thousands of patients were eligible to receive medical marijuana"); John Ingold, *Four Colorado Doctors Suspended over Medical Marijuana Recommendations*, DENVER POST (July 19, 2016), http://www.denverpost.com/2016/07/19/four-colorado-doctors-suspended-over-medical-marijuana-recommendations/ [https://perma.cc/R9Y4-BWLU] (describing medical board's revocation of licenses of four physicians for recommending "excessive plant counts to more than 1,500 patients").

274. Alan Blinder, *Doctor Loses License over Assisted Suicides*, N.Y. TIMES (Dec. 31, 2014), https://www.nytimes.com/2014/12/31/us/doctor-loses-license-over-assisted-suicides.html?_r=0 (last visited Apr. 30, 2018) (describing physician whose medical license was revoked for attending the suicides of six people "suffering from intolerable medical circumstances").

275. As one physician, who spoke with pride of losing his license for treating patients with unproven stem cell injections, said to a reporter, "I must be doing something right . . . . The greater percentage of people who get into trouble are ahead of their time." Zarembo, *supra* note 269.

276. *See* Howard L. Bailit & Cary Sennett, *Utilization Management as a Cost-Containment Strategy*, 1991 SUPP. HEALTH CARE FINANCING REV. 87 (1992); Kanika Kapur, Carole Roan Gresenz & David M. Studdert, *Managing Care: Utilization Review in Action at Two Capitated Medical Groups*, HEALTH AFFAIRS (2003).

treatments.[277] When insurers deny coverage for non-standard treatments, those treatments will end up being available only to patients who are able to provide their own funding. And unless there are a substantial number of patients both clamoring for an unconventional treatment *and* willing to pay for it out of pocket, the likelihood that physicians will continue to provide these services is low. With respect to governmental payors, moreover, the exclusionary power of Medicare and Medicaid pursuant to federal Conditions of Participation—frequently described as a "death sentence" for health care providers—can be used against physicians who do not satisfy professionally recognized standards of care.[278]

3. Institutional Standards and Hospital Credentialing

Health care institutions can also use their powers to define the boundaries of appropriate medical practice. Medical providers who work as employees or contractors within hospitals, nursing homes, and other facilities are bound by institutional policies and staff bylaws. These, along with peer review, can be used as mechanisms for limiting physicians' authority to operate outside the standard of care. In the case of the Scottish physician who amputated the healthy limbs of patients with apotemnophilia, for example, the hospital at which he performed the surgeries ultimately "announced a ban on further amputations after a report of the hospital's ethics committee."[279]

With consolidation in the health care industry at an all-time high, and the trend towards pay-for-performance incentivizing institutional management of quality and risk, health care organizations now have even more tools to define (and enforce) standards of practice among their providers.

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277. For example, cosmetic surgery, infertility treatments, weight loss surgery, home birth, experimental treatments, and alternative and complementary therapies are among the services that many health insurance policies exclude from coverage. *See, e.g.*, *Limitations and Exclusions of Aetna Health Insurance Plans*, AETNA, https://www.aetna.com/plan-info/individual/legal/limitations-exclusions.html [https://perma.cc/883T-FA4R] (identifying such exclusions in Aetna health insurance plans).

278. *See generally Exclusions Authorities*, OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUM. SERVS., https://oig.hhs.gov/exclusions/authorities.asp [https://perma.cc/C5JT-ZMNS].

279. Sabine Muller, *Body Identity Integrity Disorder (BIID): Is the Amputation of Healthy Limbs Ethically Justified?*, 9 AM. J. BIOETHICS 36, 36 (2009).

4. Legislative Prohibitions

Finally, if the medical and legal communities believe that a given approach to treatment is so extreme that it is unavoidably harmful, fundamentally inconsistent with professional norms, and lacks any societal value, state legislators could enact laws banning the treatment. State laws prohibiting the use of sexual orientation conversion therapy on minors are one example of legislative intervention aimed at protecting patients from a treatment that has been generally rejected by the medical community.[280] Laws criminalizing assistance in suicide, while not aimed at health care professionals specifically, serve a similar purpose.[281] That said, legislative intervention is a less preferable solution than medical board discipline, financial disincentives, or institutional enforcement of standards of care, as such laws are frequently driven by political motivations rather than scientific evidence or medical norms.[282]

In sum, there are many ways in which the medical profession can signal to physicians what constitutes appropriate medical practice, and there are many legal and institutional deterrents to inappropriate practice. Limiting patients' right to tort recovery when they provide voluntary and informed consent to treatment that intentionally falls outside the standard of care is not likely to dramatically lower the bar of physician practice. Today, outlier physicians providing treatments widely rejected by the medical and scientific communities do so despite public censure, license revocation, tort litigation, and even criminal charges. They do so in spite of these significant risks because patients, disillusioned with traditional medical practice, continue to seek them out. Clearly, these physicians are not deterred by the threat of malpractice liability, and elimination of that single deterrent is not likely to change their practice patterns.

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280. *See* Haldeman, *supra* note 66, at 117; Shidlo & Schroeder, *supra* note 66, at 249.

281. *See, e.g.*, Final Exit Network, Inc. v. State, 722 S.E.2d 722 (Ga. 2012) (holding GA. CODE ANN. § 16-5-5(b) (1994) to be an unconstitutional restriction of speech); State v. Melchert-Dinkel, 844 N.W.2d 13 (Minn. 2014) (holding the State could prosecute an individual for assisting another in committing suicide, but not for encouraging or advising another to commit suicide); State v. Final Exit Network, Inc., 889 N.W.2d 296 (Minn. Ct. App. 2016) (upholding statutory prohibition on assisting suicide).

282. Laws restricting access to abortion are a good example. While the medical community accepts late-term abortions and partial-birth abortions as being within the standard of care and sometimes a matter of medical necessity, legislatures have overridden the opinions of medical experts on the basis of dubious evidence. *See* Margo Kaplan, *A Special Class of Persons: Pregnant Women's Right to Refuse Medical Treatment After* Gonzales v. Carhart, 13 U. PA. J. CONST. L. 145, 158 (2011) (discussing "flimsy" evidentiary grounds for legislative finding that partial birth abortion is never medically necessary).

In contrast, some physicians may be limiting their use of innovative treatments that are safe and effective, but not yet widely accepted by the profession, simply because they fear being sued by litigious patients who don't achieve the results they hope for. The practice of defensive medicine has been widely documented,[283] and it can encompass not just providing unnecessary tests and treatments, but also not providing treatments that a jury might find do not comport with professional custom. Malpractice law's reliance on custom to define the standard of care means that highly beneficial advances in medicine—including those that have greater evidentiary support than standard practices—tend to be adopted more slowly than they should be.[284] If physicians had the confidence that a patient's informed agreement to pursue innovative treatment would free physicians from liability for proper performance of that treatment, perhaps much-needed medical innovations would be adopted sooner, rather than later, benefiting patients overall. Thus, if courts expanded the use of these defenses to other contexts, physicians would have the flexibility to modify their practice in accordance with the best evidence without fear of liability.

CONCLUSION

Courts' willingness to accept defenses to medical malpractice grounded in a patient's explicit or implicit assumption of risk in two narrow contexts—experimental and alternative treatments, and Jehovah's Witness blood refusal—demonstrates that the traditional

283. *See* Daniel Kessler & Mark McLellan, *Do Doctors Practice Defensive Medicine?*, 111 Q. J. ECON. 353 (1996) (finding that malpractice reforms that reduce the pressure of litigation also reduce medical expenditures without substantial effects on morbidity or mortality); David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609 (2005) (finding that 93% of surveyed physicians in high-risk specialties reported practicing defensive medicine, including using imaging technology when not medically necessary); OFFICE OF TECH. ASSESSMENT, OTA-H-602, DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE (1994) (describing defensive medicine practices and their prevalence).

284. *See* Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J. L. MED. 7, 14–16 (2011) (arguing that the common law system of medical malpractice liability does not keep pace with developments in medical innovation); Michael D. Greenberg, *Medical Malpractice and New Devices: Defining an Elusive Standard of Care*, 19 HEALTH MATRIX 423 (2009) (arguing that the liability risks associated with the use of new medical devices operate as a disincentive to quality improvement and technical innovation); Laakmann, *supra* note 8 (arguing that the risk of malpractice liability deters physicians from deviating from generally accepted medical practices in an attempt to improve patient care); Daniel Merenstein, *Winners and Losers*, 291 JAMA 15 (2004) (describing a lawsuit by a patient who claimed that his physician, who followed national guidelines regarding shared decision-making for PSA testing, violated the standard of care of PSA testing without patient discussion).

patient-protective view set forth in cases like *Tunkl* is not without exception. In some contexts, patients are permitted to waive their health care providers' duty to exercise due care, even though patients are traditionally viewed as vulnerable in the face of providers' superior knowledge and bargaining power.

This Article demonstrates that courts would be similarly justified in accepting these defenses in other contexts where patients seek out treatment that satisfies their personal preferences, despite the fact that it potentially falls outside the standard of care. The precedent set in the experimental treatment and blood refusal cases could be extended to many cases of "malpractice by choice," as long as the patient understands the risks and benefits of the selected treatment and its alternatives, the patient is ultimately injured by risks inherent in the treatment rather than by unanticipated negligence, and the legal factfinder views the treatment as offering some societal value. Effectively, a patient's informed consent to unorthodox treatment would operate as a defense to a medical malpractice action.

But, this Article cautions, there are risks in formalistically applying the doctrines of assumption of risk and contractual waiver of liability to the physician-patient encounter. Neither doctrine demands that a physician satisfy the disclosure obligations imposed by the common law of informed consent (including the duty to disclose his own conflicts of interest), nor that he disclose the fact that the treatment he is offering deviates from the medical profession's standard of care. As a matter of policy, however, it makes sense to require physicians who wish to benefit from defenses based on a patient's voluntary acceptance of risk to demonstrate that they have made these disclosures. The fiduciary nature of the physician-patient relationship demands these additional patient protections.

Such an approach would benefit patients who believe that unorthodox treatment is more consistent with their values and preferences and pursue it with full knowledge of its comparative risks and benefits. It would likewise benefit physicians by protecting them from liability when they offer alternative treatments sought out by patients, so long as they satisfy their legal obligation to secure the patient's informed consent and disclose the fact that they are operating outside the standard of care. It might facilitate beneficial innovation in the delivery of medical care that is otherwise stymied by malpractice liability rules that defer to customary standards and view patients as incapable of making informed decisions to pursue treatment that deviates from those standards. And it would certainly be more in line with modern views of patient autonomy in medical decision-making. If the common law of

informed consent is justified on the basis of patients' ability to understand and thoughtfully consider the risks and benefits of various types of medical treatment, then binding them to the consequences of their decisions is a natural extension of that principle.